



2021 PRIOR AUTHORIZATION CRITERIA

Essentials Rx (PPO)

Elite Rx (PPO)

Aspirus Health Plan requires your physician to get prior authorization for certain drugs. This means that you will need to get approval from Aspirus Health Plan before you fill your prescriptions. If you don't get approval, Aspirus Health Plan may not cover the drug.

Updated 12/1/2021

Notice of Nondiscrimination

Aspirus Health Plan complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. Aspirus Health Plan does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

We provide aids and services at no charge to people with disabilities to communicate effectively with us, such as TTY line, or written information in other formats, such as large print.

If you need these services, contact us at **715-631-7411 (voice)** or toll free at **1-855-931-4850 (voice)**, **715-631-7413 (TTY)**, or **1-855-931-4852 (TTY)**.

We provide language services at no charge to people whose primary language is not English, such as qualified interpreters or information written in other languages.

If you need these services, contact us at the **number on the back of your membership card** or **715-631-7411** or toll free at **1-855-931-4850 (voice)**; **715-631-7413** or toll free at **1-855-931-4852 (TTY)**.

If you believe that Aspirus Health Plan has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file an oral or written grievance.

Oral grievance

If you are a current Aspirus Health Plan member, please call the number on the back of your membership card. Otherwise please call **715-631-7411** or toll free at **1-855-931-4850 (voice)**; **715-631-7413** or toll free at **1-855-931-4852 (TTY)**. You can also use these numbers if you need assistance filing a grievance.

Written grievance

Mailing Address

Attn: Appeals and Grievances

Aspirus Health Plan

P.O. Box 51

Minneapolis, MN 55440

Email: cagMA@aspirushealthplan.com

Fax: 715-631-7439

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services

200 Independence Avenue SW

Room 509F, HHH Building

Washington, D.C. 20201

1-800-368-1019, 1-800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

XIYYEEFFANNA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 715-631-7411/1-855-931-4850 (телетайп: 715-631-7413/1-855-931-4852).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶቻችን በነጻ ሊያገለግሉት ተዘጋጅተዋል። ወደ ሚክተሎ ቁጥር ይደውሉ 715-631-7411/1-855-931-4850 (መስማት ስተሳናቸው: 715-631-7413/1-855-931-4852)።

ဝတ်သည့်ဝတ်သုံး-နမူနာကတိ ကညီ ကျိန်အယိ, နမူနာ ကျိန်အတတ်မစာလော တလက်ဘူဉ်လက်စွဲ နီတမံဘဉ်သ့န့ဉ်လီ။
ကို: 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាអង់គ្លេស, រសវាជំនួយវេជ្ជកម្មភាសា ដោយមិនគិតល្អល គឺអាចមានសំរាប់ប្រើអ្នក។ ចូរ ទូរស័ព្ទ 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم (715-631-7411/1-855-931-4850 (رقم هاتف الصم والبكم: 715-631-7413/1-855-931-4852).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 715-631-7411/1-855-931-4850 (ATS : 715-631-7413/1-855-931-4852).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852) 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 715-631-7411/1-855-931-4850 (TTY: 715-631-7413/1-855-931-4852).

ACYCLOVIR (Topical)

Products Affected

- *acyclovir topical cream*
- *acyclovir topical ointment*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medication history
Age Restrictions	acyclovir 5% cream, 12 yrs or older
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

adempas

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
Indications	All FDA-approved Indications.
Off Label Uses	

afinitor

Products Affected

- AFINITOR DISPERZ
- AFINITOR ORAL TABLET 10 MG
- *everolimus (antineoplastic) oral tablet*
2.5 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	Relapsed or refractory classical Hodgkin lymphoma-18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.

PA Criteria	Criteria Details
Other Criteria	<p>Breast Cancer-approve if the patient meets ALL the following criteria (A, B, C, D, E, and F): A) The patient has recurrent or Stage IV, hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease AND B) The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C) The patient has tried at least one prior endocrine therapy (e.g., anastrozole, letrozole, or tamoxifen) AND D) The patient meets ONE of the following conditions (i or ii): i. The patient is a postmenopausal female or a male OR ii. The patient is premenopausal or perimenopausal AND is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), or has had surgical bilateral oophorectomy or ovarian irradiation AND E) The patient meets ONE of the following conditions (i or ii): i. If patient is a male AND if everolimus will be used in combination with exemestane, the patient is receiving a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]) OR ii. everolimus will be used in combination with exemestane, Faslodex (fulvestrant intramuscular), or tamoxifen AND F) The patient has not had disease progression while on everolimus.</p> <p>Tuberous sclerosis complex (TSC) Associated subependymal giant cell astrocytoma (SEGA)-approve if the patient requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if the patient has tried one prior chemotherapy (e.g., cisplatin plus doxorubicin, cisplatin plus etoposide, carboplatin plus paclitaxel). TSC associated renal angiomyolipoma-approve.</p> <p>WM/LPL - approve if patient has progressive or relapsed disease or if the patient has not responded to ONE primary therapy (e.g., Velcade with dexamethasone with or without Rituxan, Treanda with Rituxan, Rituxan with cyclophosphamide and dexamethasone, Treanda, Velcade with or without Rituxan, Velcade with dexamethasone, Kyprolis with Rituxan and dexamethasone, Imbruvica Rituxan). Differentiated (i.e.</p>

PA Criteria	Criteria Details
	<p>papillary, follicular, and Hurthle cell) Thyroid Carcinoma-approve if the patient is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combination with letrozole and the patient has recurrent, metastatic or high-risk disease. GIST-approve if the patient has tried TWO of the following drugs: Sutent, Stivarga, or imatinib AND there is confirmation that everolimus will be used in combination with one of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. Tuberous sclerosis complex (TSC)-associated partial-onset seizures-approve.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	<p>Advanced, unresectable or metastatic neuroendocrine tumors of the thymus (Carcinoid tumors). Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma, men with breast cancer</p>

AIMOVIG

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried.
Age Restrictions	18 years and older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, β -blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician.
Indications	All FDA-approved Indications.
Off Label Uses	

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	metastatic NSCLC - is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

ALUNBRIG

Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ALK status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Metastatic NSCLC, must be ALK-positive, as detected by an approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

ampyra

Products Affected

- *dalfampridine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	MS. If prescribed by, or in consultation with, a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

anabolic steroids

Products Affected

- *oxandrolone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients w/Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia

APOKYN

Products Affected

- APOKYN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT3 Antagonist
Required Medical Information	Diagnosis, other therapies
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease (PD)-approve if the patient has advanced PD, is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried one other treatment for off episodes.
Indications	All FDA-approved Indications.
Off Label Uses	

ARALAST NP

Products Affected

- ARALAST NP INTRAVENOUS RECON
SOLN 1,000 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

arcalyst

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent biologic therapy
Required Medical Information	
Age Restrictions	Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.
Prescriber Restrictions	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum
Coverage Duration	CAPS-3 mos initial, 3 years cont. DIRA-6 mos initial, 3 years cont.Pericard-3 mos initial, 1 yr cont
Other Criteria	CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response.
Indications	All FDA-approved Indications.
Off Label Uses	

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous medication history
Age Restrictions	MAC-18 years and older
Prescriber Restrictions	MAC-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	1 year
Other Criteria	MAC Lung disease-approve if the patient has NOT achieved negative sputum cultures for Mycobacterium avium complex after a background multidrug regimen AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Cystic fibrosis pseudomonas aeruginosa infection

Austedo

Products Affected

- AUSTEDO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

avonex

Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Ayvakit

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation. Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation. Systemic mastocytosis- Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has one of the following subtypes of advanced systemic mastocytosis: aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Myeloid/Lymphoid neoplasms with Eosinophilia

BALVERSA

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

BANZEL

Products Affected

- BANZEL
- *rufinamide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Patients 1 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if the patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Continuation-approve if the patient is responding to therapy
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Treatment-Refractory Seizures/Epilepsy

BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics
Required Medical Information	Diagnosis, medications that will be used in combination, autoantibody status
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	SLE-Initial-4 months, cont-3 years. Lupus Nephritis-6 mo initial, 1 year cont

PA Criteria	Criteria Details
Other Criteria	<p>Lupus Nephritis Initial-approve if the patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]). Cont-approve if the patient has responded to the requested medication. SLE-Initial-The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

bosulif

Products Affected

- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia

BRAFTOVI

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.
Indications	All FDA-approved Indications.
Off Label Uses	

Brukinsa

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Mantle Cell Lymphoma - approve for 3 years if the patient has tried at least one prior therapy. Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve if the patient has tried at least one prior therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Chronic lymphocytic Leukemia (CLL). Small Lymphocytic Lymphoma (SLL)

C1 ESTERASE INHIBITORS

Products Affected

- CINRYZE
- HAEGARDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

cablivi

Products Affected

- CABLIVI INJECTION KIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis, concurrent medications
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Approve for 12 months
Other Criteria	aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi.
Indications	All FDA-approved Indications.
Off Label Uses	

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, histology, RET gene rearrangement status
Age Restrictions	Thyroid carcinoma-12 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Advance Renal Cell Carcinoma (Predominant Clear Cell or Non-Clear Cell Histology)-Approve. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). GIST-approve if the patient has previously tried imatinib or avapritinib and has also tried one of the following: sunitinib, regorafenib or ripretinib. Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements, Gastrointestinal stromal tumors (GIST), Bone cancer

CALQUENCE

Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	MCL, CLL and SLL-approve. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried one prior therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Non-Small Cell Lung Cancer with RET Gene Rearrangements

CARBAGLU

Products Affected

- CARBAGLU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	NAGS, no genetic test - 3 mo. NAGs, genetic test - 12 mo. Other - 7 days
Other Criteria	N-Acetylglutamate synthase deficiency with hyperammonemia- Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater than or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
Indications	All FDA-approved Indications.
Off Label Uses	

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has <i>Pseudomonas aeruginosa</i> in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off Label Uses	

CERDELGA

Products Affected

- CERDELGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, lab test results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher disease or related disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient is a cytochrome P450(CYP) 2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an approved test
Indications	All FDA-approved Indications.
Off Label Uses	

CHEMET

Products Affected

- CHEMET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Blood lead level
Age Restrictions	Approve in patients between the age of 12 months and 18 years
Prescriber Restrictions	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
Coverage Duration	Approve for 2 months
Other Criteria	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.
Indications	All FDA-approved Indications.
Off Label Uses	

chenodal

Products Affected

- CHENODAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.
Indications	All FDA-approved Indications.
Off Label Uses	

CHOLBAM

Products Affected

- CHOLBAM ORAL CAPSULE 250 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Combination Therapy with Chenodal
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with hepatologist, metabolic specialist, or GI
Coverage Duration	3 mos initial, 12 mos cont
Other Criteria	Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction.
Indications	All FDA-approved Indications.
Off Label Uses	

cialis

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Indication for which tadalafil is being prescribed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).
Indications	All FDA-approved Indications.
Off Label Uses	

CLOBAZAM

Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Lennox-Gastaut Syndrome, initial therapy-patient has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Dravet Syndrome and treatment-refractory seizures/epilepsy

cometriq

Products Affected

- COMETRIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

Continuous Glucose Monitors

Products Affected

- DEXCOM G4 RECEIVER
- DEXCOM G4 RECEIVER PEDIATRIC
- DEXCOM G4 RECEIVER-SHARE (PED)
- DEXCOM G4 RECEIVER-SHARE KIT
- DEXCOM G4 TRANSMITTER
- DEXCOM G5 RECEIVER
- DEXCOM G5 TRANSMITTER
- DEXCOM G5-G4 SENSOR
- DEXCOM G6 RECEIVER
- DEXCOM G6 SENSOR
- DEXCOM G6 TRANSMITTER
- DEXCOM RECEIVER
- FREESTYLE LIBRE 14 DAY READER
- FREESTYLE LIBRE 14 DAY SENSOR
- FREESTYLE LIBRE 2 READER
- FREESTYLE LIBRE 2 SENSOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Diabetes Mellitus - Approve if pt has been using insulin injections three or more times per day or using a Medicare-covered insulin pump AND has an insulin treatment regimen requiring frequent adjustments on the basis of blood glucose testing results. The prescriber must have had an in-person visit with the patient within the past six months to evaluate their diabetes control and that they meet the above criteria AND the patient will continue to have in-person visits every six months to assess adherence to their diabetes treatment plan. This criteria is implemented as required by Medicare Local Coverage Determination L33822.
Indications	All FDA-approved Indications.
Off Label Uses	

copaxone

Products Affected

- *glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml*
- GLATOPA SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	CLL/Follicular Lymphoma/SLL/MALT Lymphoma (gastric and non gastric)/marginal zone lymphoma-approve if the patient has tried two prior therapies
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	MALT Lymphoma (gastric and non gastric), Marginal Zone Lymphoma

COSENTYX

Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN (2 PENS)
- COSENTYX SUBCUTANEOUS SYRINGE
75 MG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	Diagnosis and previous medications use.
Age Restrictions	PP - 6 years or older. AS/PSA initial - 18 years of age and older.
Prescriber Restrictions	PP initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS initial- by or in consultation with rheumatologist, PsA initial- by or in consultation with rheumatologist or dermatologist.
Coverage Duration	PP/AS/nr-axSpA - initial tx 3 mos, PsA-initial tx 3 mos, cont tx 3 years
Other Criteria	PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PP/AS/PsA cont - patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off Label Uses	

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Melanoma initial - must have BRAF V600 mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	<p>Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma, OR ii. Recurrent disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets).</p> <p>Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions, OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease AND patient has BRAF V600 mutation-positive disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Central Nervous System Cancer, Histiocytic Neoplasm

CRESEMBA (ORAL)

Products Affected

- CRESEMBA ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Candidiasis of the esophagus - HIV infection, sepsis

CYSTARAN

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year
Other Criteria	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination.
Indications	All FDA-approved Indications.
Off Label Uses	

CYSTEAMINE (ORAL)

Products Affected

- CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Cystagon and Procysbi
Required Medical Information	Diagnosis, genetic tests and lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off Label Uses	

daliresp

Products Affected

- DALIRESP ORAL TABLET 250 MCG, 500 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.
Other Criteria	COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).
Indications	All FDA-approved Indications.
Off Label Uses	

DAURISMO

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, medications that will be used in combination, comorbidities
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	AML - approve if Daurismo will be used in combination with cytarabine AND the patient meets i. OR ii: i. patient is using Daurismo for treatment induction and is greater than or equal to 75 years old or the patient has comorbidities that preclude the use of intensive induction chemotherapy according to the prescribing physician, OR ii. patient is continuing Daurismo as post-induction therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients continuing Daurismo as post-induction therapy

DOPTELET

Products Affected

- DOPTELET (10 TAB PACK)
- DOPTELET (15 TAB PACK)
- DOPTELET (30 TAB PACK)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy only)
Coverage Duration	Thrombo w/chronic liver disease-5 days, chronic ITP- initial-3 months, continuation-3 years
Other Criteria	Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 10 ⁹ /L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP, initial-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and has tried one other therapy or if the patient has undergone splenectomy. Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off Label Uses	

DUPIXENT

Products Affected

- DUPIXENT PEN SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 ML SYRINGE 200 MG/1.14 ML, 300 MG/2 ML
- DUPIXENT SYRINGE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials
Age Restrictions	AD-6 years and older, asthma-12 years of age and older. Chronic Rhinosinusitis-18 years of age and older
Prescriber Restrictions	Atopic Dermatitis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist.
Coverage Duration	AD-Initial-4 months, Cont-1 year, asthma/Rhinosinusitis-initial-6 months, continuation 1 year

PA Criteria	Criteria Details
Other Criteria	<p>Atopic Dermatitis-Initial-meets both a and b: a.has used at least one medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid OR has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment AND b.Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician.Continuation-Approve if the pt has responded to Dupixent therapy as determined by the prescribing physician.</p> <p>Asthma-Initial-approve if pt meets the following criteria (i, ii, and iii):i.Pt meets ONE of the following criteria (a or b):a)has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR b)has oral corticosteroid-dependent asthma, per the prescriber AND ii.has received combination therapy with BOTH of the following (a and b): a)An inhaled corticosteroid (ICS) AND b)At least one additional asthma controller/maintenance medication (NOTE:An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy or Xolair used concomitantly with an ICS. Use of a combination inhaler containing both an ICS and a LABA would fulfil the requirement for both criteria a and b) AND iii.asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy or Xolair as defined by ONE of the following (a, b, c, d or e): a)experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b)experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c)has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d)has an FEV1/forced vital capacity (FVC) less than 0.80 OR e)The patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation-Approve if meets the following criteria (i and ii): i.continues to receive therapy with one inhaled</p>

PA Criteria	Criteria Details
	<p>corticosteroid (ICS) or one ICS-containing combination inhaler AND ii.has responded to Dupixent therapy as determined by the prescribing physician. Chronic rhinosinusitis with Nasal Polyposis-Initial-pt is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell according to the prescriber AND meets ONE of the following (a or b): a)has received treatment with a systemic corticosteroid within the previous 2 years or has a contraindication to systemic corticosteroid therapy OR b)has had prior surgery for nasal polyps. Continuation-approve if the pt continues to receive therapy with an intranasal corticosteroid AND pt has responded to Dupixent therapy as determined by the prescriber.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

EMGALITY

Products Affected

- EMGALITY PEN
- EMGALITY SYRINGE SUBCUTANEOUS SYRINGE 120 MG/ML, 300 MG/3 ML (100 MG/ML X 3)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, number of migraine or cluster headaches per month, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
Indications	All FDA-approved Indications.
Off Label Uses	

enbrel

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS RECON SOLN
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	PP-4 years and older (initial therapy)
Prescriber Restrictions	Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist. PP, prescribed by or in consult w/ dermatologist. GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center. Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist. Uveitis, prescribed by or in consultation with an ophthalmologist.
Coverage Duration	FDA dx-3 mo init,3 yrs cont, Behcet's/uveitis init-3 mo,cont-12 mo.GVHD-1 mo init/3 mo cont.

PA Criteria	Criteria Details
Other Criteria	<p>RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide. Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives, Humira or an infliximab product. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD, Uveitis Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice</p>
	<p>weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Graft versus host disease (GVHD), Behcet's disease, Uveitis

Enspryng

Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Soliris or Uplinza
Required Medical Information	Diagnosis, previous therapies tried, test results
Age Restrictions	NMOSD-18 years and older
Prescriber Restrictions	NMOSD-prescribed by or in consultation with a neurologist or an ophthalmologist
Coverage Duration	NMOSD - 1 year
Other Criteria	Neuromyelitis Optica Spectrum Disorder (NMSOD)- Approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years. Continuation- approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has had a clinical benefit from the use of Enspryng.
Indications	All FDA-approved Indications.
Off Label Uses	

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Patients 1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

EPOETIN ALFA

Products Affected

- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>CRF anemia in patients not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start. Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircera or Aranesp. Anemia w/myelosuppressive chemotx. pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp. MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery</p>
Age Restrictions	MDS anemia = 18 years of age and older
Prescriber Restrictions	MDS anemia/myelofibrosis, prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Chemo-6m, Transfus-1m, CKD(dialysis)-3yrs, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
Other Criteria	Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-patient has a Hgb less than or equal to 12 and according to the prescriber the patient has had a response defined as Hb greater than or equal to 10 or an increase of greater than or equal to 2 g/dL.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis

erivedge

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	BCC (La or Met) - must not have had disease progression while on Odomzo.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Central nervous System Cancer

ERLEADA

Products Affected

- ERLEADA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off Label Uses	

esbriet

Products Affected

- ESBRIET ORAL CAPSULE
- ESBRIET ORAL TABLET 267 MG, 801 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	1 year
Other Criteria	IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.
Indications	All FDA-approved Indications.
Off Label Uses	

Evrysdi

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi
Required Medical Information	Diagnosis
Age Restrictions	Greater than or equal to 2 months (initial)
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders (initial and continuation)
Coverage Duration	4 months
Other Criteria	Spinal Muscular Atrophy, Initial Treatment - Approve if the patient has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required] AND the patient meets both of the following criteria (a and b): a) has two to four survival motor neuron 2 (SMN2) gene copies [documentation required] AND b) the patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required] AND for patients who have received prior treatment with a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, the prescriber attests that further therapy with this product will be discontinued. Patients currently receiving Evrysdi approve if the patient meets the requirements for initial therapy AND has responded to Evrysdi or continues to have benefit from ongoing Evrysdi therapy by an objective measurement and/or assessment tool [documentation required].

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	

EXJADE/JADENU

Products Affected

- *deferasirox*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Serum ferritin level
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off Label Uses	

FARYDAK

Products Affected

- FARYDAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

FASENRA

Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody
Required Medical Information	Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Authorization will be for 6 months initial, 12 months continuation.

PA Criteria	Criteria Details
Other Criteria	<p>Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or Theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS for at least 3 consecutive months. Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

FERRIPROX

Products Affected

- *deferiprone*
- FERRIPROX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Serum ferritin level
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias- Initial therapy - approve if prior to starting therapy the serum ferritin level was greater than 1,000 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off Label Uses	

Filgrastim

Products Affected

- GRANIX
- NIVESTYM
- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT-3mo.Rad-1mo.All others=12mo.

PA Criteria	Criteria Details
Other Criteria	<p>Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm³], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	<p>Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).</p>

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

firazyr

Products Affected

- *icatibant*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant-the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.
Indications	All FDA-approved Indications.
Off Label Uses	

FIRDAPSE

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures (initial therapy)
Required Medical Information	Diagnosis, seizure history, lab and test results
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy)
Coverage Duration	Initial-3 months, Cont-1 year
Other Criteria	Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse, according to the prescribing physician.
Indications	All FDA-approved Indications.
Off Label Uses	

Fotivda

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.
Indications	All FDA-approved Indications.
Off Label Uses	

GATTEX

Products Affected

- GATTEX 30-VIAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced at least a 20 percent decrease from baseline in the weekly volume of parenteral nutrition.
Indications	All FDA-approved Indications.
Off Label Uses	

Gavreto

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, MTC/thyroid cancer-12 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	3 years
Other Criteria	NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Medullary thyroid cancer (MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET)-mutant disease and the disease requires treatment with systemic therapy. Thyroid cancer (other than MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET) fusion-positive disease, the disease is radioactive iodine-refractory AND the disease requires treatment with systemic therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

gilenya

Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Gilenya with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

gilotrif

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For NSCLC - EGFR exon deletions or mutations or if NSCLC is squamous cell type
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy.
Indications	All FDA-approved Indications.
Off Label Uses	

glucagon-like peptide-1 agonists

Products Affected

- BYDUREON BCISE INJECTOR 0.25 MG OR 0.5 MG(2 MG/1.5 ML), 1 MG/DOSE (2 MG/1.5 ML), 1 MG/DOSE (4 MG/3 ML)
- BYETTA SUBCUTANEOUS PEN INJECTOR 10 MCG/DOSE(250 MCG/ML) 2.4 ML, 5 MCG/DOSE (250 MCG/ML) 1.2 ML
- OZEMPIC SUBCUTANEOUS PEN
- RYBELSUS
- TRULICITY
- VICTOZA 3-PAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- *leuprolide subcutaneous kit*
- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	For the treatment of cancer diagnosis must be prescribed by or in consultation with an oncologist.
Coverage Duration	For abnormal uterine bleeding, uterine leiomyomata 6 mo. All other=12 mo
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors

growth hormones

Products Affected

- OMNITROPE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>GHD in Children/Adolescents. Pt meets one of the following-1- had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy</p>
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.

PA Criteria	Criteria Details
Coverage Duration	ISS - 6 mos initial, 12 months cont tx, SBS-1 month, others 12 mos
Other Criteria	<p>GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by</p>

PA Criteria	Criteria Details
	<p>chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	SHOX, Noonan Syndrome, CKD, SBS

HETLIOZ

Products Affected

- HETLIOZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-24-patient is totally blind with no perception of light
Age Restrictions	Non-24-18 years or older, SMS-16 years and older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial - dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if pt has achieved adequate results with HetlioZ therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)-approve.
Indications	All FDA-approved Indications.
Off Label Uses	

high risk medications - benzodiazepines

Products Affected

- *alprazolam oral tablet*
- *clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg*
- *diazepam oral concentrate*
- *diazepam oral solution 5 mg/5 ml (1 mg/ml)*
- *diazepam oral tablet*
- LORAZEPAM INTENSOL
- *lorazepam oral tablet 0.5 mg, 1 mg, 2 mg*
- *oxazepam*
- *temazepam oral capsule 15 mg, 30 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 12 months.
Other Criteria	All medically accepted indications other than insomnia, authorize use. Insomnia, may approve lorazepam, temazepam, or oxazepam if the patient has had a trial with two of the following: ramelteon, trazodone, doxepin 3mg or 6 mg. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

HIGH RISK MEDICATIONS - BENZTROPINE

Products Affected

- *benztropine oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

HIGH RISK MEDICATIONS - CHLORZOXAZONE

Products Affected

- *chlorzoxazone oral tablet 500 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- *cyclobenzaprine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

high risk medications - first generation antihistamines

Products Affected

- *hydroxyzine hcl oral tablet*
- *promethazine oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- *phenobarbital*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for use in sedation/insomnia.
Required Medical Information	
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For the treatment of seizures, approve only if the patient is currently taking phenobarbital.
Indications	All Medically-accepted Indications.
Off Label Uses	

humira

Products Affected

- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UEVITS-ADOL HS
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML
- HUMIRA(CF) PEDI CROHNS STARTER SUBCUTANEOUS SYRINGE KIT 80 MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4 ML
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PEDIATRIC UC
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC), 5 or older (initial therapy only).
Prescriber Restrictions	Initial therapy only for all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist. UV-ophthalmologist
Coverage Duration	initial 3 mo, cont tx 3 years.

PA Criteria	Criteria Details
Other Criteria	<p>RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone), or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced (metastatic) hormone receptor positive (HR+) [i.e., estrogen receptor positive- {ER+} and/or progesterone receptor positive {PR+}] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Liposarcoma

iclusig

Products Affected

- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restrictions	CML/ALL - Adults
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	CML Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Philadelphia chromosome positive CML (e.g., Gleevec, Sprycel, Tasigna). ALL Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.)
Indications	All FDA-approved Indications.
Off Label Uses	

IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	IDH2-mutation status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
Indications	All FDA-approved Indications.
Off Label Uses	

IMATINIB

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	For ALL/CML, must have Ph-positive for approval of imatinib. AIDS related Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, AIDS Related Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor.

imbruvica

Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	GVHD-1 year, all others-3 years
Other Criteria	Marginal Zone Lymphoma - Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib, Jakafi). B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician. Central nervous system Lymphoma (primary)/Hairy Cell Leukemia-approve if relapsed or refractory.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorders).

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone cypionate intramuscular oil 100 mg/ml, 200 mg/ml*
- *testosterone enanthate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, lab results
Age Restrictions	Delayed puberty or induction of puberty in males-14 years and older
Prescriber Restrictions	
Coverage Duration	Delayed puberty or induction of puberty in males-6 months, all others-12 months

PA Criteria	Criteria Details
Other Criteria	<p>Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Female-to-male transsexual - Gender dysphoria

inlyta

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Advanced renal cell carcinoma, approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease.
Indications	All FDA-approved Indications.
Off Label Uses	

IRESSA

Products Affected

- IRESSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

Isturisa

Products Affected

- ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior surgeries
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease
Coverage Duration	1 year
Other Criteria	Cushing's Disease - Approve if the patient is not a candidate for surgery or surgery has not been curative.
Indications	All FDA-approved Indications.
Off Label Uses	

ivig

Products Affected

- GAMMAKED INJECTION SOLUTION 1 GRAM/10 ML (10 %)
- GAMUNEX-C INJECTION SOLUTION 1 GRAM/10 ML (10 %)
- PRIVIGEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home.
Indications	All Medically-accepted Indications.
Off Label Uses	

jakafi

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	ALL-less than 21 years of age
Prescriber Restrictions	
Coverage Duration	GVHD/ALL-1 year, all others-Authorization will be for 3 years.
Other Criteria	For polycythemia vera patients must have tried hydroxyurea. ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease. GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Acute lymphoblastic leukemia, graft versus host disease, chronic, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2)

juxtapid

Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Kynamro, Praluent, or Repatha.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	<p>Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

KALYDECO

Products Affected

- KALYDECO ORAL GRANULES IN PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Orkambi, Trikafta or Symdeko
Required Medical Information	
Age Restrictions	4 months of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - must have one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off Label Uses	

KISQALI

Products Affected

- KISQALI
- KISQALI FEMARA CO-PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years

PA Criteria	Criteria Details
Other Criteria	<p>Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following</p> <ol style="list-style-type: none"> 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole. Patients must have a trial of Ibrance prior to approval of Kisqali/Kisqali Femara Co-Pack unless the patient meets one of the following- <ol style="list-style-type: none"> a) Patient has been taking Kisqali or Kisqali Femara Co-Pack and is continuing therapy OR b) Patient is pre/perimenopausal and will be using Kisqali or Kisqali Femara Co-Pack in combination with an aromatase inhibitor as initial endocrine-based therapy OR c) Kisqali will be used in combination with fulvestrant in postmenopausal female or male patients as initial endocrine-based therapy
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Men with breast cancer

KORLYM

Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior surgeries
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome.
Coverage Duration	Cushing's-1 year. Patients awaiting surgery or response after radiotherapy-4 months
Other Criteria	Endogenous Cushing's Syndrome-Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if Korlym is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy

Koselugo

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Neurofibromatosis Type 1 - approve if the patient is 2 to 18 years of age OR the patient is 19 years of age or older and has been previously started on therapy with Koselugo prior to becoming 19 years of age, AND prior to starting Koselugo the patient has symptomatic, inoperable plexiform neurofibromas, according to the prescriber.
Indications	All FDA-approved Indications.
Off Label Uses	

KUVAN

Products Affected

- KUVAN
- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq (continuation only)
Required Medical Information	Diagnosis, Phe concentration
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
Coverage Duration	Initial-12 weeks, Continuation-1 year
Other Criteria	Initial - approve. Continuation - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20% or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance.
Indications	All FDA-approved Indications.
Off Label Uses	

Kynmobi

Products Affected

- KYNMOBI SUBLINGUAL FILM 10 MG, 15 MG, 20 MG, 25 MG, 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's Disease-Approve if the patient is experiencing off episodes, such as muscle stiffness, slow movements or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried one other treatment for off episodes.
Indications	All FDA-approved Indications.
Off Label Uses	

Ledipasvir-Sofosbuvir

Products Affected

- *ledipasvir-sofosbuvir*

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Indications consistent with current AASLD/IDSA guidance.

LENVIMA

Products Affected

- LENVIMA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	DTC - must be refractory to radioactive iodine treatment for approval. RCC, advanced disease - approve if the pt meets i or ii: i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b: a. Patient has clear cell histology and patient has tried one antiangiogenic therapy OR b. patient has non-clear cell histology. MTC-approve if the patient has tried Caprelsa or Cometriq. Anaplastic thyroid cancer-approve if the disease does not have a curative option. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Patients with Medullary Thyroid Carcinoma (MTC) and anaplastic thyroid carcinoma.

letairis/tracleer

Products Affected

- *ambrisentan*
- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
Age Restrictions	
Prescriber Restrictions	For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Authorization will be for 3 years.
Other Criteria	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)

LEUKINE

Products Affected

- LEUKINE INJECTION RECON SOLN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Neuroblastoma-less than 18 years of age
Prescriber Restrictions	AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome. Neuroblastoma-prescribed by or in consultation with an oncologist.
Coverage Duration	Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days
Other Criteria	Neuroblastoma-approve if the patient is receiving Leukine in a regimen with dinutuximab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neuroblastoma

LIDOCAINE PATCH

Products Affected

- *lidocaine topical adhesive patch, medicated 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Diabetic neuropathic pain, chronic back pain

LONG ACTING OPIOIDS

Products Affected

- BELBUCA *mg/5 ml*
- *buprenorphine*
- *hydrocodone bitartrate oral capsule, oral only, er 12hr*
- *hydromorphone oral tablet extended release 24 hr*
- *methadone oral solution 10 mg/5 ml, 5*
- *methadone oral tablet 10 mg, 5 mg*
- *morphine oral capsule, er multiphase 24 hr*
- *morphine oral capsule, extend.release pellets*
- *morphine oral tablet extended release*

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.

PA Criteria	Criteria Details
Other Criteria	<p>For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive (not required for buprenorphine products), AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Gastric or Gastroesophageal Junction Adenocarcinoma-approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.
Indications	All FDA-approved Indications.
Off Label Uses	

LORBRENA

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, ALK status, ROS1 status, previous therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	NSCLC - Approve if the patient has ALK-positive metastatic NSCLC. NSCLC-ROS1 Rearrangement-Positive-approve if the patient has tried one of crizotinib, entrectinib or ceritinib.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive

Lumakras

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be 3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen.
Indications	All FDA-approved Indications.
Off Label Uses	

lynparza

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years

PA Criteria	Criteria Details
Other Criteria	<p>Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria (i and ii): i. patient has a germline BRCA-mutation as confirmed by an approved test AND per product labeling the patient has progressed on three or more prior lines of chemotherapy. Continuation-approve if the patient has a BRCA mutation (germline) as confirmed by an approved test.</p> <p>Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B)The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combo tx-approve if Lynparza is used in combo with bevacizumab, pt has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and pt is in complete or partial response to first-line platinum-based chemotherapy regimen.</p> <p>Breast Cancer-Approve if the patient meets the following criteria (A, B, and C)-A. The patient has metastatic, germline BRCA mutation-positive breast cancer AND B. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1-The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND C. The patient has been treated with</p>

PA Criteria	Criteria Details
	<p>chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if pt has metastatic disease, Lynparza is used concurrently with a GnRH analog or pt has had a bilateral orchiectomy, pt has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test, pt does not have a PPP2R2A mutation and pt has been previously treated with abiraterone or Xtandi.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

MAVYRET

Products Affected

- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Current AASLD/IDSA guidance and, if not available, FDA labeling
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance and, if not available, FDA labeling.
Indications	All FDA-approved Indications.
Off Label Uses	

Mayzent

Products Affected

- MAYZENT
- MAYZENT STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

megace

Products Affected

- *megestrol oral suspension 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml)*
- *megestrol oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight gain for cosmetic reasons.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

mekinist

Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.

PA Criteria	Criteria Details
Other Criteria	<p>Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, unless intolerant AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma, OR ii. Recurrent disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafenlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions, OR patient has Erdheim Chester disease or Rosai-Dorfman disease AND patient has BRAF V600-mutation positive disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Biliary Tract Cancer, Central Nervous System Cancer, Histiocytic Neoplasm.

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Colon or rectal cancer

memantine

Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet*
- NAMZARIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with mild to moderate vascular dementia.

MIGLUSTAT

Products Affected

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher disease or related disorders
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Modafinil/Armodafinil

Products Affected

- *armodafinil*
- *modafinil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Fatigue due to MS - 18 years of age and older. All others - 17 years of age and older.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive daytime sleepiness associated with Shift Work Sleep Disorder (SWSD)-approve if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Fatigue due to multiple sclerosis - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only. Fatigue due to multiple sclerosis - modafinil only.

MULPLETA

Products Affected

- MULPLETA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	7 days
Other Criteria	Approve if the patient has a current platelet count less than 50 x 10 ⁹ /L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

myalept

Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist
Coverage Duration	Authorization will be for 3 years.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

NATPARA

Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	1 year
Other Criteria	Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND the patient is responding to Natpara therapy, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off Label Uses	

NAYZILAM

Products Affected

- NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off Label Uses	

Nerlynx

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-3yrs
Other Criteria	Breast cancer adjuvant therapy - approve if the patient meets all of the following criteria: Patient has HER2-positive breast cancer AND patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, advanced or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens in the metastatic setting.
Indications	All FDA-approved Indications.
Off Label Uses	

nexavar

Products Affected

- NEXAVAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: imatinib mesylate (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test. Renal cell carcinoma (RCC)-approve if the patient has relapsed or Stage IV clear cell histology and the patient has tried at least one prior systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar is used in combination with topotecan.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Osteosarcoma, angiosarcoma, desmoids tumors (aggressive fibromatosis), gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer

NILUTAMIDE

Products Affected

- *nilutamide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.
Indications	All FDA-approved Indications.
Off Label Uses	

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MM - be used in combination with Revlimid and dexamethasone OR pt had received at least ONE previous therapy for multiple myeloma (e.g., Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone) OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma

NITYR/ORFADIN

Products Affected

- *nitisinone*
- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of therapy with nitisinone products
Required Medical Information	Diagnosis, genetic tests and lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Hereditary Tyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone.
Indications	All FDA-approved Indications.
Off Label Uses	

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)*
 - *testosterone transdermal gel in packet*
- 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)*
- *testosterone transdermal solution in metered pump w/app*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.

PA Criteria	Criteria Details
Other Criteria	<p>Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]</p>
Indications	All FDA-approved Indications.
Off Label Uses	

nothera

Products Affected

- *droxidopa*
- NORTHERA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medication history
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist
Coverage Duration	12 months
Other Criteria	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine
Indications	All FDA-approved Indications.
Off Label Uses	

NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off Label Uses	

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

NUPLAZID

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Nurtec ODT

Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
Exclusion Criteria	Combination Therapy with Aimovig, Ajovy, Emgality, or Vyepti.
Required Medical Information	Diagnosis, other therapies used
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine, acute treatment Pt has tried at least one triptan therapy or has a contraindication to triptans according to the prescriber. Preventive Treatment of Episodic Migraine-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has experienced adverse event(s) severe enough to warrant discontinuation.
Indications	All FDA-approved Indications.
Off Label Uses	

ocaliva

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following: a) Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b) Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c) Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)).
Indications	All FDA-approved Indications.
Off Label Uses	

Odactra

Products Affected

- ODACTRA

PA Criteria	Criteria Details
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	Greater than or equal to 18 years of age
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	House Dust Mite (HDM)-Induced Allergic Rhinitis (AR)-approve if the diagnosis is confirmed by meeting ONE of the following conditions (i or ii): i. The patient has a positive skin test response to house dust mite allergen extracts OR ii. The patient has a positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite (HDM).
Indications	All FDA-approved Indications.
Off Label Uses	

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Metastatic BCC

ofev

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	1 year
Other Criteria	IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.
Indications	All FDA-approved Indications.
Off Label Uses	

Omnipod

Products Affected

- OMNIPOD DASH 5 PACK POD
- OMNIPOD INSULIN MANAGEMENT
- OMNIPOD INSULIN REFILL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, insulin usage
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Diabetes mellitus, type 1 - approve. Diabetes mellitus, type 2, insulin dependent - approve if pt is using at least three injections of insulin per day. Continuation - approve.
Indications	All FDA-approved Indications.
Off Label Uses	

Ongentys

Products Affected

- ONGENTYS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's Disease- Approve if the patient is currently receiving carbidopa/levodopa therapy or Ongentys.
Indications	All FDA-approved Indications.
Off Label Uses	

Onureg

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	AML - Approve if the patient meets the following criteria (both A and B): A)Following intensive induction chemotherapy, the patient achieves one of the following according to the prescriber (i or ii): i. First complete remission OR ii. First complete remission with incomplete blood count recovery AND B) Patient is not able to complete intensive curative therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

opsumit

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PAH WHO group, right heart catheterization
Age Restrictions	
Prescriber Restrictions	PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 3 years
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications.
Off Label Uses	

orencia

Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE
125 MG/ML, 50 MG/0.4 ML, 87.5
MG/0.7 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	
Prescriber Restrictions	Initial therapy only-RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	SC-3 mos initial, 3 years cont
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], approve if the patient has tried one other agent for this condition or the patient will be starting on Orencia concurrently with methotrexate, sulfasalazine or leflunomide or the patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide or the patient has aggressive disease as determined by the prescribing physician. Cont tx - responded to therapy as per the prescriber.
Indications	All FDA-approved Indications.
Off Label Uses	

Orgovyx

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Prostate Cancer-approve.
Indications	All FDA-approved Indications.
Off Label Uses	

Oriahnn

Products Affected

- ORIAHNN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
Coverage Duration	24 months of total therapy
Other Criteria	Heavy menstrual bleeding associated with uterine fibroids- approve if the patient is premenopausal and uterine fibroids have been confirmed by a pelvic ultrasound, hysteroscopy or magnetic resonance imaging.
Indications	All FDA-approved Indications.
Off Label Uses	

ORILISSA

Products Affected

- ORILISSA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe hepatic impairment, osteoporosis
Required Medical Information	Diagnosis, previous medications
Age Restrictions	18 years of age and older
Prescriber Restrictions	
Coverage Duration	Initial - 6 months. Total approval duration not to exceed 24 months (150 mg once daily dosing)
Other Criteria	Initial, approve if patient has moderate to severe endometriosis pain and has tried one of the following: a contraceptive (combination oral contraceptives, levonorgestrel-releasing intrauterine systems), or a progesterone product unless contraindicated, an exception to the requirement for a trial of the above can be made if there has been prior trial of a gonadotropin-releasing hormone (GnRH) agonist, AND the patient has continued to experience moderate to severe pain associated with endometriosis after treatment with one of the above mentioned agents, unless contraindicated. Continuation, approve if the patient has responded to treatment as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off Label Uses	

ORKAMBI

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Kalydeco, Trikafta or Symdeko.
Required Medical Information	
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)
Indications	All FDA-approved Indications.
Off Label Uses	

Orladeyo

Products Affected

- ORLADEYO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro).
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values [documentation required] AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required]. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline [documentation required to confirm diagnosis of HAE type I or II for continuation].
Indications	All FDA-approved Indications.
Off Label Uses	

otezla

Products Affected

- OTEZLA
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous drugs tried
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	All dx-initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	4 months initial, 3 years cont
Other Criteria	PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA initial-approve if the patient has tried at least one conventional synthetic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant (note: pts who have already tried a biologic DMARD are not required to step back and try a conventional DMARD first). Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	

Oxervate

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, an ophthalmologist or optometrist.
Coverage Duration	2 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

PALYNZIQ

Products Affected

- PALYNZIQ SUBCUTANEOUS SYRINGE
10 MG/0.5 ML, 2.5 MG/0.5 ML, 20
MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, phenylalanine concentrations
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year (initial and continuation)
Other Criteria	Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.
Indications	All FDA-approved Indications.
Off Label Uses	

Panretin

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist
Coverage Duration	1 year
Other Criteria	Kaposi Sarcoma related to Acquired Immunodeficiency Syndrome - approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.
Indications	All FDA-approved Indications.
Off Label Uses	

PDE5 Inhibitors

Products Affected

- ALYQ *tablet*
- sildenafil (*pulm.hypertension*) oral suspension for reconstitution
- sildenafil (*pulm.hypertension*) oral *tablet*
- tadalafil (*pulm. hypertension*) *tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PAH - diagnosis, right heart cath results. Raynaud phenomenon - diagnosis, previous medications
Age Restrictions	
Prescriber Restrictions	PAH - prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception. Raynaud phenomenon - must have previous trial and failure of one CCB, such as amlodipine or nifedipine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Raynaud phenomenon

PEGASYS

Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION
- PEGASYS SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Pegfilgrastim

Products Affected

- FULPHILA
- UDENYCA
- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 mo
Other Criteria	Cancer Patients Receiving Chemotherapy - approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients undergoing PBPC collection and therapy

PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen
Indications	All FDA-approved Indications.
Off Label Uses	

PENICILLAMINE

Products Affected

- *penicillamine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
Coverage Duration	3 years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

PHENYL BUTYRATE

Products Affected

- RAVICTI
- *sodium phenylbutyrate*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Ravicti and Buphenyl
Required Medical Information	Diagnosis, genetic tests and lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
Other Criteria	Urea cycle disorders-approve if genetic testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia.
Indications	All FDA-approved Indications.
Off Label Uses	

PHEOCHROMOCYTOMA

Products Affected

- DEMSER
- *metyrosine*
- *phenoxybenzamine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior medication trials
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.
Indications	All FDA-approved Indications.
Off Label Uses	

PIQRAY

Products Affected

- PIQRAY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female or a male or premenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) analog AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene) AND F) Piqray will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Treatment of breast cancer in premenopausal women

PLEGRIDY

Products Affected

- PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML
- PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). CNS Lymphoma-approve if the patient has relapsed or refractory disease
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma

PRALUENT

Products Affected

- PRALUENT PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Juxtapid or Repatha.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
Age Restrictions	18 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Hyperlipidemia in patients with HeFH-approve if meets all of the following 1. Pt has been diagnosed with HeFH AND 2. Provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both. Hyperlipidemia Pt with Clinical ASCVD - approve if meets all of the following: has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, Provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both. Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	

PROLASTIN C

Products Affected

- PROLASTIN-C INTRAVENOUS RECON SOLN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

promacta

Products Affected

- PROMACTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
Age Restrictions	
Prescriber Restrictions	Thrombocytopenia due to chronic ITP or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist. Thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease. MDS-presc or after consult with heme/onc.
Coverage Duration	Chronic ITP - 3 years, others 12 months.

PA Criteria	Criteria Details
Other Criteria	<p>Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, approve if the patient has tried ONE other therapy or has undergone a splenectomy. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy if the patient has low platelet counts (eg, less than 75,000 mm³) and the patient has chronic HCV infection and is a candidate for hepatitis C therapy. Aplastic anemia - has low platelet counts at baseline/pretreatment (e.g., less than 30,000 mm³) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. MDS-approve if patient has low- to intermediate-risk MDS AND according to the prescriber the patient has clinically-significant thrombocytopenia (e.g., low platelet counts [pretreatment], is platelet transfusion-dependent, active bleeding, and/or a history of bleeding at low platelet counts).</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Thrombocytopenia in Myelodysplastic Syndrome (MDS)

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient's immune status
Age Restrictions	
Prescriber Restrictions	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
Coverage Duration	12 months
Other Criteria	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Gastrointestinal stromal tumor (GIST), advanced-approve if, according to labeling, the patient has been previously treated with imatinib and at least two other kinase inhibitors, in addition to imatinib.
Indications	All FDA-approved Indications.
Off Label Uses	

rebif

Products Affected

- REBIF (WITH ALBUMIN) MCG/0.5ML (6)
- REBIF REBIDOSE SUBCUTANEOUS PEN INJECTOR 22 MCG/0.5 ML, 44 MCG/0.5 ML, 8.8MCG/0.2ML-22
- REBIF TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

RELISTOR

Products Affected

- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

REPATHA

Products Affected

- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Juxtapid or Praluent.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Approve for 3 years for ASCVD/HeFH/HoFH/primary hyperlipidemia.

PA Criteria	Criteria Details
Other Criteria	<p>Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) Provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both. Hyperlipidemia with ASCVD - approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) Provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both. HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both. Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)- approve if the provider attests that the patient has tried at least ONE statin and/or ezetimibe and was unable to meet LDL goals of lower than 70 mg/dL after 8 weeks with maximally tolerated therapy or is intolerant of both.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

RETEVMO

Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer-12 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is RET fusion-positive. Medullary Thyroid Cancer-approve if the patient has advanced or metastatic RET-mutant disease and the disease requires treatment with systemic therapy. Thyroid Cancer-approve if the patient has advanced or metastatic RET fusion positive disease, the disease is radioactive iodine-refractory (if radioactive iodine is appropriate) and the disease requires treatment with systemic therapy. Anaplastic thyroid cancer-approve if the patient has RET fusion-positive anaplastic thyroid carcinoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Anaplastic thyroid carcinoma

revlimid

Products Affected

- REVLIMID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.

PA Criteria	Criteria Details
Other Criteria	<p>Follicular lymphoma-approve if the patient is using Revlimid in combination with rituximab or has tried at least on prior therapy. MCL-approve. MZL-approve. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/ml. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS cancers (primary)-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has relapsed or refractory disease. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. AIDS Related Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	<p>Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system cancer (primary), Acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma.</p>

RINVOQ

Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	18 years and older
Prescriber Restrictions	RA, prescribed by or in consultation with a rheumatologist.
Coverage Duration	Authorization will be for 3 months initial, 3 years cont.
Other Criteria	RA initial-approve if the patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). Continuation Therapy - Patient must have responded, as determined by the prescriber
Indications	All FDA-approved Indications.
Off Label Uses	

Rozlytrek

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Solid Tumors-12 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Solid Tumors-Approve if the patient meets the following criteria (A, B, and C): A) The patient has locally advanced or metastatic solid tumor AND B) The patient's tumor has neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND C) The patient meets one of the following criteria (i or ii): i. The patient has progressed on prior therapies OR ii. There are no acceptable standard therapies and the medication is used as initial therapy. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.
Indications	All FDA-approved Indications.
Off Label Uses	

rubraca

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years
Other Criteria	Ovarian, Fallopian Tube or Primary Peritoneal Cancer-treatment-Approve if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy. Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For AML, FLT3 status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	AML-approve if the patient is FLT3-mutation positive as detected by an approved test AND the patient is receiving Rydapt in one of the following settings (i, ii, iii, or iv)-i. Induction therapy in combination with cytarabine and daunorubicin OR ii. After standard-dose cytarabine induction/reinduction, along with cytarabine and daunorubicin OR iii. Post remission or consolidation therapy in combination with cytarabine OR iv. Maintenance therapy. Myeloid or lymphoid neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Myeloid or lymphoid neoplasms with eosinophilia

samsca

Products Affected

- SAMSCA ORAL TABLET 15 MG
- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Jynarque.
Required Medical Information	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 30 days
Other Criteria	Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
Coverage Duration	Cushing's disease Initial - 4 mo, Cont - 1 year. Pt awaiting surgery or radiotherapy response - 4 mo
Other Criteria	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
Indications	All FDA-approved Indications.
Off Label Uses	

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 15 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 5 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis, Pulmonary Multidrug-resistant or extensively drug resistant-prescribed as part of a combination regimen with other anti-tuberculosis agents
Indications	All FDA-approved Indications.
Off Label Uses	

Skyrizi

Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML
- SKYRIZI SUBCUTANEOUS SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Initial - 3 months. Continuation - 1 year
Other Criteria	<p>Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis) b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician.</p> <p>Continuation Therapy - Patient must have responded, as determined by the prescriber.</p>

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	

Sofosbuvir-Velpatasvir

Products Affected

- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Indications consistent with current AASLD/IDSA guidance.

solaraze

Products Affected

- *diclofenac sodium topical gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 6 months.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.
Indications	All FDA-approved Indications.
Off Label Uses	

sprycel

Products Affected

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - has D842V mutation AND previously tried Sutent and Gleevec.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	GIST, chondrosarcoma, chordoma

stelara

Products Affected

- STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	18 years and older-UC/CD (initial therapy). PP-6 years and older (initial therapy).
Prescriber Restrictions	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	PP/PsA Init-3mo,CD/UC load-approve 1 dose IV,CD/UC post IV load-SC 3 mo, cont tx-SC 3 yr
Other Criteria	PP initial - Approve Stelara SC. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. CD, initial therapy (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	

stivarga

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). For HCC, patient must have previously been treated with at least one tyrosine kinase inhibitor (e.g., Nexavar, Lenvima). Soft tissue sarcoma-approve if the patient has non-adipocytic extremity/superficial trunk, head/neck or retroperitoneal/intra-abdominal sarcoma OR pleomorphic rhabdomyosarcoma. Osteosarcoma-approve if the patient has relapsed/refractory or metastatic disease and the requested medication is being used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Soft tissue Sarcoma, Osteosarcoma

SUCRAID

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient sucrase or isomaltase activity in duodenal or jejunal biopsy specimens OR patient has a sucrose hydrogen breath test OR has a molecular genetic test demonstrating sucrose-isomaltase mutation in saliva or blood.
Indications	All FDA-approved Indications.
Off Label Uses	

sutent

Products Affected

- *sunitinib*
- SUTENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has previously tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or Stage IV disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma.

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	Six years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - must be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off Label Uses	

SYNAREL

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping, as detected by an approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax.
Required Medical Information	Diagnosis, genetic tests and lab results.
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy),ii. Amyloid deposits are identified on cardiac biopsy OR iii. patient had genetic testing which, according to the prescriber, identified a TTR mutation AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum).
Indications	All FDA-approved Indications.
Off Label Uses	

tafinlar

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.

PA Criteria	Criteria Details
Other Criteria	<p>Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma, OR ii. Recurrent disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions, OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm

TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	NSCLC - Must have metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND has progressed on one of the EGFR tyrosine kinase inhibitors (e.g., Tarceva, Iressa, Vizimpro or Gilotrif) therapy OR Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test. NSCLC, EGFR Mutation positive-approve if the medication is used as adjuvant therapy after tumor resection and the tumor is positive for EGFR exon 19 deletions or exon 21 L858R mutations as detected by an approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

TALZENNA

Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, BRCA mutation status, HER2 status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Locally-advanced or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease
Indications	All FDA-approved Indications.
Off Label Uses	

tarceva

Products Affected

- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status, pancreatic cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Advanced RCC, approve if the patient has non-clear cell histology. Bone cancer-chordoma-approve if the patient has tried imatinib, dasatinib or sunitinib.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Renal Cell Carcinoma and Bone Cancer-Chordoma.

TARGRETIN ORAL

Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

TARGRETIN TOPICAL

Products Affected

- TARGRETIN TOPICAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

tasigna

Products Affected

- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and ALL, prior therapies tried.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO of the following - sunitinib (Sutent), imatinib (Gleevec), or regorafenib (Stivarga). For ALL, Approve if the patient has tried one other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST).

TAZAROTENE

Products Affected

- *tazarotene topical cream*
- TAZORAC TOPICAL CREAM 0.05 %
- TAZORAC TOPICAL GEL

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).
Indications	All Medically-accepted Indications.
Off Label Uses	

Tazverik

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Epithelioid Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and according to the prescriber, there are no appropriate alternative therapies or the patient's tumor is positive for an EZH2 mutation and the patient has tried at least two prior systemic therapies.
Indications	All FDA-approved Indications.
Off Label Uses	

tecfidera

Products Affected

- *dimethyl fumarate oral capsule, delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg*
- TECFIDERA ORAL CAPSULE, DELAYED RELEASE(DR/EC) 120 MG, 120 MG (14)- 240 MG (46), 240 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Tepmetko

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	NSCLC-approve if the patient has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Indications	All FDA-approved Indications.
Off Label Uses	

TERIPARATIDE

Products Affected

- *teriparatide*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Fortical], abaloparatide), except calcium and Vitamin D.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 years

PA Criteria	Criteria Details
Other Criteria	<p>Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. Patients who have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

thalomid

Products Affected

- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.

PA Criteria	Criteria Details
Other Criteria	<p>Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). AIDS Related Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease, is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8) and has hyaline vascular histology.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, AIDS related Kaposi's Sarcoma, Castleman's Disease.

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen. Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Cholangiocarcinoma, Chondrosarcoma

Tiopronin

Products Affected

- *tiopronin*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with a nephrologist, urologist, or physician who specializes in the treatment of cystinuria.
Coverage Duration	1 year
Other Criteria	Cystinuria - Approve if the diagnosis of cystinuria has been confirmed based on laboratory testing (e.g., urinary cystine crystals present on microscopy, quantitative urine cystine assay).
Indications	All FDA-approved Indications.
Off Label Uses	

TOLCAPONE

Products Affected

- *tolcapone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, current medications and medication history
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease-approve if the patient is currently receiving carbidopa/levodopa therapy and the patient has tried entacapone and according to the prescriber, experienced unacceptable tolerability or could not achieve adequate benefit.
Indications	All FDA-approved Indications.
Off Label Uses	

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- *pimecrolimus*
- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All Medically-accepted Indications.
Off Label Uses	

topical retinoid products

Products Affected

- AVITA TOPICAL CREAM
- *tretinoin*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

topiramate/zonisamide

Products Affected

- *topiramate oral capsule, sprinkle*
- *topiramate oral tablet*
- *zonisamide*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

TRANSDERMAL FENTANYL

Products Affected

- *fentanyl transdermal patch 72 hour*
100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

PA Criteria	Criteria Details
Exclusion Criteria	Acute (i.e., non-chronic) pain.
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	

transmucosal fentanyl drugs

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off Label Uses	

TRIENTINE

Products Affected

- *trientine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, medication history, pregnancy status, disease manifestations
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	'Authorization will be for 3 years.
Other Criteria	For Wilson's Disease, approve if the patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant.
Indications	All FDA-approved Indications.
Off Label Uses	

Trikafta

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.
Required Medical Information	Diagnosis, specific CFTR gene mutations, concurrent medications
Age Restrictions	6 years or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off Label Uses	

Truseltiq

Products Affected

- TRUSELTIQ ORAL CAPSULE 100 MG/DAY (100 MG X 1), 125 MG/DAY(100 MG X1-25MG X1), 50 MG/DAY (25 MG X 2), 75 MG/DAY (25 MG X 3)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test and Truseltiq will be used as subsequent therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

TUKYSA

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Breast Cancer-approve if the patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine.
Indications	All FDA-approved Indications.
Off Label Uses	

TURALIO

Products Affected

- TURALIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)- approve if, according to the prescriber, the tumor is not amenable to improvement with surgery. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Histiocytic Neoplasms

tykerb

Products Affected

- *lapatinib*
- TYKERB

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	HER2-positive advanced or metastatic breast cancer, approve if the patient has received prior therapy with trastuzumab and lapatinib will be used in combination with capecitabine OR lapatinib will be used in combination with trastuzumab. HER2-positive HR positive metastatic breast cancer, approve if the patient is a man receiving a GnRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian radiation or a postmenopausal woman and lapatinib will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or exemestane. In this criteria, man/woman is defined as an individual with the biological traits of a man/woman, regardless of the individual's gender identity or expression. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and the medication is used as subsequent therapy in combination with trastuzumab and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-chordoma-approve if the patient has epidermal growth-factor receptor (EGFR)-positive recurrent disease.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Bone cancer-chordoma, colon or rectal cancer

Ukoniq

Products Affected

- UKONIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Follicular Lymphoma-approve if the patient has received at least three prior lines of systemic therapy. Marginal Zone Lymphoma-approve if the patient has received at least one prior anti-CD20-based regimen.
Indications	All FDA-approved Indications.
Off Label Uses	

UPTRAVI

Products Affected

- UPTRAVI ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmation of right heart catheterization, medication history.
Age Restrictions	
Prescriber Restrictions	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).
Indications	All FDA-approved Indications.
Off Label Uses	

VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Adults with T-cell leukemia/lymphoma

Valtoco

Products Affected

- VALTOCO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off Label Uses	

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	CLL with or without 17p deletion - approve. SLL-approve. Mantle Cell Lymphoma-approve if the patient has tried one prior therapy. AML-approve if the patient is using Venclexta in combination with either azacitidine, decitabine, or cytarabine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Mantle Cell Lymphoma

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years

PA Criteria	Criteria Details
Other Criteria	<p>Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following</p> <ol style="list-style-type: none"> 1. Pt is postmenopausal and Verzenio will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Verzenio will be used in combination with anastrozole, exemestane, or letrozole 3. Patient is postmenopausal and meets the following conditions: Verzenio will be used in combination with fulvestrant. 4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND Verzenio will be used in combination with fulvestrant 5. patient is postmenopausal, premenopausal, /perimenopausal (patient is receiving ovarian suppression/ablation with GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has progressed on at least one prior endocrine therapy (e.g., anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol) AND patient has tried chemotherapy for metastatic breast cancer. 6. pt is a man who is receiving GnRH analog AND Verzenio with be used in combination with anastrozole, exemestane or letrozole 7. Patient is a man and Verzenio will be used in combination with fulvestrant.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Men with breast cancer

VIGABATRIN

Products Affected

- *vigabatrin*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

VITRAKVI

Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, NTRK gene fusion status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Solid tumors - approve if the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments or the patient has disease progression following treatment.
Indications	All FDA-approved Indications.
Off Label Uses	

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Metastatic-NSCLC-Epidermal Growth Factor Receptor (EGFR) mutation positive AND has epidermal growth factor receptor (EGFR) exon 19 deletion as detected by an approved test OR exon 21 (L858R) substitution mutations as detected by an approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

VOSEVI

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Current AASLD/IDSA guidance and, if not available, FDA labeling.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance and, if not available, FDA labeling.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Off-label uses consistent with current AASLD/IDSA guidance

votrient

Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Soft tissue sarcoma other than GIST [angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or solitary fibrous tumor/hemangiopericytoma or alveolar soft part sarcoma], approve. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent, advanced or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma.

Vumerity

Products Affected

- VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Welireg

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, and B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.
Indications	All FDA-approved Indications.
Off Label Uses	

xalkori

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1. For soft tissue sarcoma IMT, ALK translocation.
Age Restrictions	Anaplastic large cell lymphoma-patients greater than or equal to 1 year of age and less than 21 years of age
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC, must be ALK-positive as detected by an approved test, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, NSCLC with high level MET amplification or MET Exon 14 skipping mutation.

xeljanz

Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	
Prescriber Restrictions	RA, JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	PsA/RA/JIA/JRA-3 months initial, UC-16 weeks initial, All diagnoses-3 years cont.

PA Criteria	Criteria Details
Other Criteria	<p>RA/PsA initial, approve Xeljanz/XR if the patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). UC-Approve Xeljanz/XR if the patient has had a trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthritis/active sacroiliac arthritis]-initial-approve Xeljanz tablets (not the XR formulation) or oral solution if the patient meets ONE of the following: patient has tried one other medication (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic also counts as a trial of one medication.) for this condition OR Patient has aggressive disease. Continuation Therapy - Patient must have responded, as determined by the prescriber.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

xenazine

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.

Xenleta

Products Affected

- XENLETA ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	Community Acquired Pneumonia: Diagnosis must be confirmed via chest radiograph AND The member has a documented intolerance, adverse reaction, or resistance to at least two formulary alternatives from different antibiotic classes approved for CAP (macrolides, fluoroquinolones, beta-lactam, tetracycline (doxycycline)).
Indications	All FDA-approved Indications.
Off Label Uses	

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

xolair

Products Affected

- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody
Required Medical Information	Moderate to severe persistent asthma, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine).
Age Restrictions	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older
Prescriber Restrictions	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist
Coverage Duration	asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months

PA Criteria	Criteria Details
Other Criteria	<p>Moderate to severe persistent asthma approve if pt meets criteria 1 and 2. 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following- long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2)patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 consecutive months. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. Nasal Polyps Initial- Approve if the patient has a baseline IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, FLT3-mutation status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid, or Mixed Lineage Neoplasms- approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Lymphoid, Myeloid, or Mixed Lineage Neoplasms

XPOVIO

Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (40 MG X 1), 40MG TWICE WEEK (40 MG X 2), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (40 MG X 2), 80MG TWICE WEEK (160 MG/WEEK)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years

PA Criteria	Criteria Details
Other Criteria	<p>Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with Darzalex (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma-approve if the patient has been treated with at least two prior systemic therapies.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

xtandi

Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Xtandi is being used.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Prostate cancer-castration-resistant (CRPC) [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off Label Uses	

XURIDEN

Products Affected

- XURIDEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a metabolic specialist, geneticist or physician specializing in the condition being treated
Coverage Duration	1 year
Other Criteria	Hereditary orotic aciduria (Orotic aciduria Type 1)-Approve if the patient has molecular genetic testing confirming mutation in the UMPS gene or clinical diagnosis supported by first degree family relative (i.e., parent or sibling) with hereditary orotic aciduria and urinary orotic acid level above the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off Label Uses	

xyrem

Products Affected

- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medication history
Age Restrictions	
Prescriber Restrictions	Prescribed by a sleep specialist physician or a Neurologist
Coverage Duration	12 months.
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off Label Uses	

YONSA

Products Affected

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, concomitant medications
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone.
Indications	All FDA-approved Indications.
Off Label Uses	

ZEJULA

Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen. Ovarian, fallopian tube, or primary peritoneal cancer, treatment-approve per label if the patient has tried at least three prior chemotherapy regimens and has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test.
Indications	All FDA-approved Indications.
Off Label Uses	

zelboraf

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresctable, advanced or metastatic melanoma. HCL - must have relapsed or refractory disease AND tried at least one other therapy for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with the BRAF V600 mutation-approve. Central Nervous System Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma, OR ii. Recurrent disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. Multisystem disease OR ii. Pulmonary disease OR iii. Central nervous system lesions AND the patient has BRAF V600-mutation positive disease.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off Label Uses	

zydelig

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	CLL-approve if the patient has tried two prior therapies. Marginal Zone Lymphoma/Follicular Lymphoma/SLL - approve if the patient has tried two prior therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Marginal Zone Lymphoma

zykadia

Products Affected

- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test or ROS1 Rearrangement. IMT - ALK Translocation status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement-First-line therapy.

zytiga

Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*
- ZYTIGA ORAL TABLET 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if abiraterone is being used in combination with prednisone and the medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant], Firmagon) OR ii. Patient has had an orchiectomy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Prostate Cancer-Regional Risk Group.

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