



## Prior Authorization Criteria Updates Effective June 1, 2022

### UCare Individual & Family Plans UCare Individual & Family Plans with M Health Fairview

On June 1, 2022, prior authorization criteria for the drugs listed below will be updated. These changes will be reflected in the [2022 Prior Authorization Criteria](#) document.

<b>Alecensa</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Anaplastic Large Cell Lymphoma.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, mutation results
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Non-Small Cell Lung Cancer (NSCLC) - Approve if the pt has metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung disease. Anaplastic Large Cell Lymphoma - Approve if pt has anaplastic lymphoma kinase (ALK)-positive disease.

<b>Arcalyst</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	Concurrent use with other biologic therapies for an inflammatory condition. COVID-19
<b>Required Medical</b>	Diagnosis, genetic testing

<b>Information</b>	
<b>Age Restrictions</b>	CAPS/Pericarditis - 12 years and older
<b>Prescriber Restrictions</b>	CAPS - Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. IL-1 RA- Prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders.
<b>Coverage Duration</b>	Initial - 6 months. Continuation - 1 year.
<b>Other Criteria</b>	Cryopyrin-Associated Periodic Syndromes (CAPS) [Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease or chronic infantile neurological cutaneous and articular syndrome]- Initial - Approve. Deficiency of Interleukin-1 Receptor Antagonist (IL-1 RA)- Initial - approve if pt is greater than 10 kg (22 lbs) AND genetic testing has confirmed a mutation in the IL1RN gene and according to the prescriber, patient has demonstrated a clinical benefit with Kineret. Pericarditis - Approve if pt has recurrent pericarditis with a history of at least three episodes of pericarditis in the past AND pt is currently receiving standard treatment or standard treatment is contraindicated. Continuation for all - Approve if pt has been established on therapy for 6 months and, when compared to baseline, pt has experienced a beneficial clinical response as assessed by at least one objective measure or improvement in at least one symptom.

<b>Cabometyx</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Bone Cancer. Endometrial Carcinoma. Gastrointestinal Stromal Tumors. Non-Small Cell Lung Cancer.
<b>Exclusion Criteria</b>	Metastatic Castration-Resistant Prostate Cancer
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, mutation status
<b>Age Restrictions</b>	HCC/RCC/Endometrial carcinoma/GIST/NSCLC - 18 years or older. Thyroid carcinoma - 12 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Hepatocellular Carcinoma (HCC) - Approve if pt has been previously treated with at least one systemic therapy. Renal Cell Carcinoma

	<p>(RCC) - Approve if pt has relapsed or stage IV disease. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma, is refractory to radioactive iodine therapy, and has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. Bone Cancer - Approve if pt has tried at least one previous systemic regimen and has Ewing sarcoma or osteosarcoma. Endometrial Carcinoma - Approve if pt has tried one systemic regimen. Gastrointestinal Stromal Tumors (GIST) - Approve if pt has tried imatinib or Ayvakit (avapritinib), Sutent (sunitinib) or Sprycel (dasatinib), Stivarga (regorafenib), and Qinlock (ripretinib). Non-Small Cell Lung Cancer (NSCLC) - Approve if tumor is positive for RET rearrangements.</p>
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<b>Dalfampridine ER</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	ambulation evaluation measures
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
<b>Coverage Duration</b>	Initial - 4 months. Continuation - 1 year.
<b>Other Criteria</b>	Multiple Sclerosis - Approve if pt is ambulatory but has impaired ambulation as evaluated by an objective measure, and the requested medication is being used to improve or maintain mobility. Continuation - Approve if pt is ambulatory, the requested medication is being used to improve or maintain mobility, and the pt has experienced an improvement or maintenance in walking speed or other objective measures related to ambulation.

<b>Everolimus (antineoplastic)</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Endometrial Carcinoma. Gastrointestinal Stromal Tumors (GIST). Histiocytic Neoplasm (HN). Classic Hodgkin Lymphoma. Meningioma. Soft Tissue Sarcoma. Thymomas and Thymic Carcinomas. Differentiated Thyroid Carcinoma. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL).

<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	diagnosis, hormone receptor status, prior therapies
<b>Age Restrictions</b>	Breast cancer/NE tumors/RCC/TSC with RA/TC/EC/GIST/CHL/HN/Meningioma/STS/TTC/WM/LPL - 18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	<p>Breast Cancer - Approve if pt has recurrent or metastatic, hormone receptor Positive (HR+) disease and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND pt has tried at least one prior endocrine therapy (anastrozole, letrozole, or tamoxifen), AND pt meets one of the following: pt is a postmenopausal woman or a man OR pt is a pre-or perimenopausal woman receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide, triptorelin, goserelin), or has had surgical bilateral oophorectomy or ovarian irradiation AND pt meets one of the following: if pt is a male and if everolimus will be used in combination with exemestane, then the patient is receiving a GnRH analog OR everolimus will be used in combination with exemestane, fulvestrant or tamoxifen AND the pt has not had disease progression while on everolimus. Neuroendocrine Tumors of the Pancreas, Gastrointestinal Tract, Lung, and Thymus (Carcinoid Tumors) - Approve. Renal Cell Carcinoma (RCC) - Pt has relapsed or stage IV disease. If using for clear cell disease, the pt has tried a systemic therapy previously (e.g. axitinib, pazopanib, sunitinib, cabozantinib, sorafenib). Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma - approve. TSC-Associated Subependymal Giant Cell Astrocytoma (SEGA) - Approve if SEGA cannot be curatively resected. TSC-Associated Partial Onset Seizure - approve. Differentiated Thyroid Carcinoma -Approve if refractory to radioactive iodine therapy. Endometrial Carcinoma - Approve if everolimus will be used in combination with letrozole. GIST - Pt has tried imatinib or avapritinib, sunitinib or dasatinib, regorafenib, ripretinib and everolimus will be used in combination with imatinib, sunitinib, or regorafenib. Histiocytic Neoplasm - Approve if pt has a PIK3CA mutation and one of the following: Erdheim-Chester disease, Rosai-Dorfman disease, or Langerhans cell histiocytosis with bone disease, central nervous system lesions, multisystem disease, or pulmonary disease. Classical Hodgkin Lymphoma - approve if pt has refractory or relapsed disease. Meningioma - Approve if pt has recurrent or progressive disease. Soft Tissue Sarcoma - Approve if pt has perivascular epithelioid cell tumor (PEComa) or recurrent angiomyolipoma/lymphangiomyomatosis. Thymomas and Thymic Carcinomas - Approve if pt has tried chemotherapy or pt cannot tolerate chemotherapy. Thyroid</p>

	carcinoma, differentiated - Approve if pt has has differentiated thyroid carcinoma (e.g. papillary, follicular, and Hürthle cell thyroid carcinoma) and the disease is refractory to radioactive iodine therapy. WM/LPL - Approve if pt has not responded to primary therapy or pt has progressive or relapsed disease.
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<b>Growth Hormone</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Short Bowel Syndrome in Adults.
<b>Exclusion Criteria</b>	Acute Critical Illness Due to Complications Following Surgery, Multiple Accidental Trauma, or with Acute Respiratory Failure. Aging, To Improve Functional Status in Elderly Patients, and Somatopause. Athletic Ability Enhancement. Central Precocious Puberty. Chronic Fatigue Syndrome. Congenital Adrenal Hyperplasia (CAH). Constitutional Delay of Growth and Puberty (CDGP). Corticosteroid-Induced Short Stature. Fibromyalgia. Human Immunodeficiency Virus (HIV)-Infected Patients with Alterations in Body Fat Distribution. Infertility. Obesity. Osteoporosis.
<b>Required Medical Information</b>	Diagnosis, lab results [documentation required], vitals
<b>Age Restrictions</b>	NGHDSS - 5 years or younger. Children Born Small for Gestational Age or with Intrauterine Growth Restriction (initial) - 2 years or older. SBS - 18 years or older.
<b>Prescriber Restrictions</b>	GHD, Noonan, PWS, SHOX, born small - eval by endocrinologist. CKD - eval by endocrinologist or a nephrologist.
<b>Coverage Duration</b>	NGHDSS (initial) - 6 months. SBS (initial and cont) - 1 mo. All others - 1 year
<b>Other Criteria</b>	GHD-Child/Adolescent - Pt meets one of the following: pt has had 2 GH tests with inadequate reponse OR pt has had 1 GH test with inadequate response and has at least 1 risk factor for GHD; pt has undergone brain radiation or tumor resection and either has had 1 GH test with an inadequate response or pt has a deficiency in at least 1 other pituitary hormone; pt has congenital hypopituitarism and either has had 1 GH test with an inadequate response, pt has a deficiency in at least 1 other pituitary hormone, or pt has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk; pt has panhypopituitarism either has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic

	<p>posterior pituitary "bright spot" on magnetic resonance image or computed tomography, pt has 3 or more pituitary deficiencies, or pt has had 1 GH test with an inadequate response; or pt has had a hypophysectomy.</p> <p>Short Stature - Pt is at least 5 yo, pts ht is less than 1.2% or SDS - 2.25, velocity is less than 4cm/yr or less than 10th percentile, without GH adult ht is 63 in for M or 59 in for F, the epiphyses are open and pt does not have constitutional delay of growth and puberty. Cont-x6-10mo: Pt is at least 5 yo and growth rate has doubled.</p> <p>GHD in Adult/Transition Adolescent - Not being used for anti-aging therapy or to enhance athletic ability or for body building; documentation of childhood onset, adult onset from multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage; pt has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects or 3 pituitary hormone deficiencies with a low serum insulin-like growth factor-1 due to GHD; adult pt has had a negative response to GH stim test or transition adolescent pt has been off somatropin for 1 month and has inadequate GH stim test (see policy).</p> <p>CKD Child/Adolescent-Approve if pt has CKD.</p> <p>Noonan-Baseline ht is less than 5th percentile.</p> <p>Prader-Willi Syndrome-Approve.</p> <p>Short Stature Homeobox (SHOX) - Approve if pt has SHOX deficiency, epiphyses are open, and ht is less than 3rd percentile.</p> <p>Born Small/Silver-Russell Syndrome - Approve if pt was born 2 standard deviations below mean birth wt/ht and height remains less than 5th percentile.</p> <p>Turner Syndrome - Approve.</p> <p>Short Bowel Syndrome - Approve if pt is receiving nutritional support.</p> <p>Cont - Approve if prescriber attests to response.</p> <p>Cont (CKD, Noonan, PWS,SHOX,Tumer) - Approve if height increased by 2 cm/hr and epiphyses are open.</p> <p>Cont (CHD, Born Small, SS w/ tx longer than 10mo) - Ht has increased by 2cm/yr, if greater than 11 yo epiphysis are open, and if 18yo, mid parental height has not be obtained.</p>
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<b>Idhifa</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from coverage.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Mutation results
<b>Age</b>	18 years or older

<b>Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Acute Myeloid Leukemia (AML) - approve if the disease is isocitrate dehydrogenase-2 (IDH2)-mutation positive as detected by an approved test.

<b>Immune Globulin</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	For Vivaglobin, Hizentra prescribed with one of the following physician specialists: an allergist/immunologist, immunologist, otolaryngologist (ear nose and throat [ENT] physician), pulmonologist, or an infectious disease specialist
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For Gammunex-C, Gammaked, Gammagard liquid given SC and Vivaglobin, Hizentra, needs to be used for the treatment of a primary humoral or combined immune deficiency, which includes common variable immunodeficiency (CVID), X-linked agammaglobulinemia, severe combined immunodeficiencies (SCID), Wiskott-Aldrich syndrome, hyper-IgM syndromes (X-linked or autosomal recessive), other combined immunodeficiencies with significant hypogammaglobulinemia or antibody production defect, and unspecified hypogammaglobulinemia. For Gammunex-C, Gammked, Gammagard, other IVIG given IV, need documented diagnosis, prescriber specialty. For Vivaglobin, Hizentra, diagnoses Common variable immunodeficiency (CVID) and Unspecified hypogammaglobulinemia patient has documented history of significant recurrent or persistent, severe bacterial infections (such as recurrent pneumonias, frequent episodes of bacterial infections such as sinusitis, otitis, bronchitis, skin structure infections, or infections of the gastrointestinal tract) according to the prescribing physician that are not responding to antibiotics or prophylactic antibiotics or member has interfering hypersensitivities, other disorders increasing susceptibility to infection need to have been sought out and treated if exist, patient has reduced IgG level or reduced IgG1 and IgG3 levels

	or IgG1 reduction. Other immune deficiencies for Hizentra, Vivaglobin, patient has frequent and severe infections.
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<b>Jakafi</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Atypical Chronic Myeloid Leukemia. Chronic Monomyelocytic Leukemia-2. Essential Thrombocythemia. Myeloid or Lymphoid Neoplasms.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Previous therapies tried. Mutation results.
<b>Age Restrictions</b>	GVHD - 12 years or older. MF/PV/CML-2/ET/MLN - 18 years or older. ALL - 21 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Graft versus Host Disease, Acute - Approve if pt has tried one systemic corticosteroid. Graft versus Host Disease, Chronic - Approve if pt has tried one conventional systemic treatment for graft versus host disease. Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF - approve. Polycythemia Vera (PV) - Approve if pt has tried hydroxyurea. Acute Lymphoblastic Leukemia (ALL) - Approve if the mutation/pathway is Janus Associated Kinase-related. Atypical Chronic Myeloid Leukemia - Approve if pt has a CSF3R mutation or a Janus Associated Kinase 2 rearrangement. Chronic Monomyelocytic Leukemia-2 (CML-2) - Approve if pt is also receiving a hypomethylating agent. Essential Thrombocytopenia - Approve if pt has tried hydroxyurea, peginterferon alfa-2a, or anagrelide. Myeloid or Lymphoid Neoplasms - Approve if pt has eosinophliia and the tumor has a Janus Associated Kinase 2 (JAK2) rearrangement.

<b>Livtencity</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	
<b>Required Medical</b>	Diagnosis, weight

<b>Information</b>	
<b>Age Restrictions</b>	12 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center
<b>Coverage Duration</b>	2 months
<b>Other Criteria</b>	Cytomegalovirus Infection - Treatment (CMV) - Approve if pt weights at least 35 kg (77 lbs), the pt is post-transplant, Livtency is not prescribed in conjunction with ganciclovir or valganciclovir, and the patients CMV is refractory to treatment with one of cidofovir, foscarnet, ganciclovir, or valganciclovir or the pt has significant intolerance to ganciclovir or valganciclovir.

<b>Lonsurf</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, mutation results
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Colon and Rectal Cancer - Approve if pt has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil [5-FU]), oxaliplatin, and irinotecan, and if the pt's tumor or metastases are KRAS and NRAS mutation negative, then Erbitux or Vectibix has been tried. Gastric or Gastroesophageal Junction Adenocarcinoma - Approve if pt has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.

<b>Onureg</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Myeloid or Lymphoid Neoplasms.
<b>Exclusion</b>	

<b>Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, mutation results
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Acute Myeloid Leukemia - Approve if pt is FLT3-mutation positive AML as detected by an approved test. Aggressive Systemic Mastocytosis (ASM) - Approve. Systemic Mastocytosis Associated with Acute Hematologic Neoplasm - Approve. Mast Cell Leukemia - approve. Myeloid or Lymphoid Neoplasms - Approve if pt has eosinophilia and an FGFR1 rearrangement or an FLT3 rearrangement.

<b>Rydapt</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Myeloid or Lymphoid Neoplasms.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, mutation results
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Acute Myeloid Leukemia - Approve if pt is FLT3-mutation positive AML as detected by an approved test. Aggressive Systemic Mastocytosis (ASM) - Approve. Systemic Mastocytosis Associated with Acute Hematologic Neoplasm - Approve. Mast Cell Leukemia - approve. Myeloid or Lymphoid Neoplasms - Approve if pt has eosinophilia and an FGFR1 rearrangement or an FLT3 rearrangement.

<b>Scemblix</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.

<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, mutation results, previous therapies tried
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Chronic Myeloid Leukemia - approve if pt has Philadelphia chromosome positive chronic myeloid leukemia and the chronic myeloid leukemia is T315I-positive or pt has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia.

<b>Tazverik</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, mutation results
<b>Age Restrictions</b>	16 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Epithelioid Sarcoma - Approve if pt has metastatic or locally advanced disease and is not eligible for complete resection. Follicular Lymphoma - Approve if pt has relapsed or refractory disease and meets one of the following: tumor is positive for an EZH2 mutation and pt has tried at least two prior systemic therapies or according to the prescriber, there are no appropriate alternative therapies.

<b>Teriparatide</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	Concurrent use with other medications for osteoporosis (Prolia, oral bisphosphonates, calcitonin nasal spray, Tymlos, and Evenity). Osteoporosis prevention.

<b>Required Medical Information</b>	diagnosis, other therapies tried, lab results
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Hypoparathyroidism - prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Pt at high risk of fracture - 2 years. Not at high risk of fracture - up to 2 years/lifetime
<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis, Treatment - approve if pt is either initiating or continuing systemic glucocorticoids and meets one of the following: pt has tried zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical condition OR pt has severe renal impairment, chronic kidney disease, or has had an osteoporotic fracture or a fragility fracture. Use of teriparatide exceeding 2 years during a patient's lifetime will only be approved if the patient is at high risk for fracture as determined by the prescriber.</p> <p>Osteoporosis, Treatment for a Postmenopausal Patient and Osteoporosis, (to Increase Bone Mass) in Men with Primary or Hypogonadal Osteoporosis - Approve if pt has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius, has had an osteoporotic fracture or a fragility fracture, or has low bone mass and is at risk for fracture. Pt also meets one of the following: pt has tried ibandronate injection (Postmenopausal pts only) or zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical condition OR pt has severe renal impairment, chronic kidney disease, or has had an osteoporotic fracture or a fragility fracture. Use of teriparatide exceeding 2 years during a patient's lifetime will only be approved if the patient is at high risk for fracture as determined by the prescriber.</p> <p>Hypoparathyroidism - Approve if pt has tried Natpara or Natpara is unavailable.</p>

<b>Tibsovo</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded. Bone Cancer.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, mutation results
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Acute Myeloid Leukemia (AML) - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Cholangiocarcinoma - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and pt has been previously treated with at least one chemotherapy regimen. Bone Cancer - Approve if pt has chondrosarcoma and disease is isocitrate dehydrogenase-1 (IDH1) mutation positive.

<b>Voxogo</b>	
<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
<b>Exclusion Criteria</b>	Hypochondroplasia, Thanatophoric Dysplasia, or other Short Stature Conditions other than Achondroplasia (e.g., trisomy 21, pseudoachondroplasia). Concurrent Treatment with Growth Hormone (e.g., somatropin), Long-Acting Growth Hormone (e.g., lonapegsomatropin), or Insulin-like Growth Factor- 1 (IGF-1) [i.e., Increlex® {mecasermin}] Agents.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	5-17 years old
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pediatric endocrinologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acondroplasia - Approve if the diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, the pts

	<p>epiphyses are open and there is evidence of annualized growth velocity of at least 1.5 cm/year, pt will not not have limb-lengthening surgery during treatment with Voxzogo, and the prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration. Continuation - Approve if pt continues to meet initial criteria and pts most recent annualized growth velocity continues to be above their baseline annualized growth velocity value prior to starting on Voxzogo.</p>
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