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AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.

TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).



**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

**COVERAGE DURATION:** All indications (initial, reauth): 12 months

**OTHER CRITERIA:** All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.

AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.

TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

**COVERAGE DURATION:** All indications (initial, reauth): 12 months

**OTHER CRITERIA:** All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.

AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.

TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

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- COVERED USES:** All medically accepted indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:**
- REQUIRED INFO:** Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA.
- AGE RESTRICTIONS:**
- MD RESTRICTIONS:** PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.
- COVERAGE DURATION:** PBC (initial): 6 months, (reauth): 12 months
- OTHER CRITERIA:** PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior Ocaliva therapy) while on Ocaliva therapy.

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:** All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

**REQUIRED INFO:** Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG  $\hat{\Delta}$  Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than  $10 \times 10^9/L$ . 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm<sup>3</sup>. 5) Post-transfusion purpura. Continued in Other Criteria Section.

**AGE RESTRICTIONS:** HIV (initial): patient is less than or equal to 12 years of age.

**MD RESTRICTIONS:** All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

**COVERAGE DURATION:** 4 months: Solid organ transplant. 12 months: all other diagnoses.

**OTHER CRITERIA:**

[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

## OCTREOTIDE ACETATE

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) History of failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION:** All Uses (Initial and reauth): 12 months

**OTHER CRITERIA:** Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.



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**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Esbriet (pirfenidone).

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** IPF (initial): Prescribed by a pulmonologist

**COVERAGE DURATION:** Initial, reauth: 12 months

**OTHER CRITERIA:** IPF (reauth): Documentation of positive clinical response to Ofev therapy.

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

**COVERAGE DURATION:** All indications (initial, reauth): 12 months

**OTHER CRITERIA:** All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.

AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.

TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m<sup>2</sup>, at or below 8mcg/L if BMI at or above 25 and below 30kg/m<sup>2</sup>, or at or below 4mcg/L if BMI at or above 30kg/m<sup>2</sup>], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

**COVERAGE DURATION:** PAH: Initial: 6 months. Reauth: 12 months.

**OTHER CRITERIA:** PAH (Reauth): Documentation of positive clinical response to therapy.

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**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Orencia therapy. Patient is not receiving Orencia in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.

**COVERAGE DURATION:** All indications (Initial, reauth): 12 months

**OTHER CRITERIA:** All indications (Reauth): Documentation of positive clinical response to Orencia therapy. Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

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**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Orencia therapy. Patient is not receiving Orencia in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.

**COVERAGE DURATION:** All indications (Initial, reauth): 12 months

**OTHER CRITERIA:** All indications (Reauth): Documentation of positive clinical response to Orencia therapy. Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

## ORENITRAM

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

**COVERAGE DURATION:** PAH: Initial: 6 months. Reauth: 12 months.

**OTHER CRITERIA:** PAH (Reauth): Documentation of positive clinical response to therapy.

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**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments-approved facility.

**AGE RESTRICTIONS:** CF (Initial): Patient is 6 years of age or older

**MD RESTRICTIONS:** CF (Initial): Prescribed by or in consultation with a pulmonologist

**COVERAGE DURATION:** CF (initial, reauth): 12 months

**OTHER CRITERIA:** CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)



**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, OR for continuation of prior Otezla therapy.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.

**COVERAGE DURATION:** Initial, Reauth: 12 months

**OTHER CRITERIA:** Reauthorization (all indications): Documentation of positive clinical response to Otezla therapy.

## OXANDROLONE

**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Oxandrin will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:**

**COVERAGE DURATION:** bone pain (initial, reauth): 1 month. Others (initial, reauth): 3 months

**OTHER CRITERIA:** All diagnoses (reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, or reduction in muscle pain/weakness)











































































































































































































**COVERED USES:** All medically accepted indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA:**

**REQUIRED INFO:** Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive.

**AGE RESTRICTIONS:**

**MD RESTRICTIONS:** Prescribed by or in consultation with a gastroenterologist.

**COVERAGE DURATION:** SBS: 4 weeks.

**OTHER CRITERIA:**