S5617 Formulary Prior Auth Criteria Summary (Pages 1-2):

Abraxane	
Actimmune	
Actiq	5
Adagen	6
Agrylin	7
Alpha-1 Proteinase Inhibitor Therapy	8
Amevive	
Apokyn	
Aranesp and Epoetin Alfa	11
Arava	
Aredia	
Atgam	
Botox	
Byetta	
Cancidas	
Carnitor	
Celebrex	
Cerezyme	
Chelation Therapy	
Compounded Drug Therapies	
Copaxone	
CytoGam	
Enbrel	
Flolan	
Forteo	
Gleevec	
Granulocyte Colony Stimulating Factor Therapy	
Growth Hormone	
Histrelin	
Humira	
IGIM	
Increlex™	
Infergen	
lplex™	
Injectable Drugs, Not Otherwise Specified	
lressa	43
IVIG	44
Kineret	46
Leukine	47
Leuprolide	48
Lyrica	49
Mobic	50
Multiple Sclerosis Interferon Therapy	
Mycamine	
Myobloc	
Neumega	
Nexavar® (sorafenib)	
Octreotide	56

Onychomycosis Antifungal Therapy	57
Orencia	58
Panretin	59
Pegylated Interferon Therapy	60
Penlac	61
Plenaxis	62
Proleukin	63
Provigil	64
Raptiva	65
Regranex	66
Remicade	67
Remodulin	69
Revatio	70
Revlimid	71
Rituxan	72
Secreflo	73
Somavert	74
Symlin	75
Synagis	76
Synarel	78
Tagretin	79
Tarceva	80
Trelstar	81
Tretinoin	82
Vaccine Prior Auth Criteria, Not Otherwise Specified	83
Velcade	84
Ventavis	85
Vesanoid	86
VFEND	87
Viadur	88
Vidaza	89
Xolair	90
Zoladex	91
Zometa	92
Zyvox	93

Abraxane Prior Auth Criteria:

CIGNA HealthCare covers paclitaxel protein-bound particles (Abraxane®) as medically necessary

when BOTH of the following indications are met:

- Treatment is for breast cancer after failure of combination chemotherapy for metastatic disease or
- relapse within six months of adjuvant chemotherapy.
- Prior therapy should have included an anthracycline (like doxorubicin or epirubicin) unless
- clinically contraindicated.

Actimmune Prior Auth Criteria:

CIGNA HealthCare covers interferon gamma-1b (Actimmune®) as medically necessary when

ANY of the following indications are met:

- to reduce the frequency and severity of serious infections associated with chronic granulomatous disease
- to delay time to disease progression in patients with severe, malignant osteopetrosis
- treatment of idiopathic pulmonary fibrosis (IPF)

Actiq Prior Auth Criteria:

CIGNA Pharmacy Management covers oral transmucosal fentanyl citrate (Actiq) when the following medical necessity criteria are met:

 Treatment of breakthrough cancer pain where patients are already receiving and are tolerant to opioid therapy

CIGNA HealthCare does not cover transmucosal fentanyl citrate (Actiq®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- treatment of types of pain other than breakthrough cancer pain
- when patient is not tolerant to opioid therapy
 Note: Prior authorization is required; approval may be given for up to six months with a quantity limit of four units per day.

Adagen Prior Auth Criteria:

CIGNA Pharmacy Management covers pegademase (Adagen $^{\text{\tiny M}}$) as medically necessary when the following indication is met:

• Diagnosis of adenosine deaminase deficiency

CIGNA Pharmacy Management does not cover pegademase (Adagen™) for the following indications, because it is considered experimental, investigational or unproven (this list may not be all inclusive):

• Preparation of support therapy for bone marrow transplantation

Agrylin Prior Auth Criteria:

CIGNA Pharmacy Management covers Agrylin when the following medical necessity criteria are met:

- For second line treatment of essential thrombocythemia after failure with Hydrea (hydroxyurea.)
- For first line treatment of essential thrombocythemia in patients at risk of developing leukemia (Hydrea is contraindicated in leukemia patients.)

Alpha-1 Proteinase Inhibitor Therapy Prior Auth Criteria:

Alpha-1 Proteinase Inhibitor Therapy includes the following drugs:

- Aralast®
- Prolastin®
- Zemaira®

CIGNA Pharmacy Management covers alpha-1 proteinase inhibitor therapy when the following medical necessity criteria are met:

- Diagnosis of congenital alpha-1 antitrypsin deficiency (AATD),
- intravenous therapy only.

CIGNA Pharmacy Management does not cover alpha-1 proteinase inhibitor therapy because it is considered not medically necessary or of unproven benefit for the following diagnoses (this list may not be all-inclusive):

 Diagnosis of congenital alpha-1 antitrypsin deficiency (AATD) as Inhalation therapy

Amevive Prior Auth Criteria:

CIGNA HealthCare covers alefacept (Amevive®) as medically necessary for the treatment of moderate-to-severe chronic plaque psoriasis when ALL of the following criteria are met:

- The patient is age 18 or older.
- At least 10% of the body surface area (BSA) is affected.
- There has been previous use of any one topical therapy (e.g., corticosteroids, Tazorac, Dovonex,

anthralin, salicylic acids, tars) for six months.

• The patient is a candidate for ONE of the following types of systemic therapy OR phototherapy :

methotrexate, cyclosporine, or soriatane narrow or broad band ultraviolet B (UVB), or psoralen plus ultraviolet A (PUVA)

Note: Coverage may be approved for up to 12 weeks. Coverage may be approved for re-treatment ONCE as long as the total lymphocyte and CD4+ T cell counts are within normal range and a minimum of 12 weeks has passed since the last course of therapy. Data on re-treatment beyond two cycles are limited.

CIGNA HealthCare does not cover alefacept (Amevive®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- treatment of rheumatoid arthritis
- treatment of active psoriatic arthritis

Apokyn Prior Auth Criteria:

CIGNA Pharmacy Management covers Apomorphine (Apokyn™) as medically necessary when all of the following indications are met:

- Diagnosis of Advanced Parkinson's Disease and,
- Experiencing hypomobility despite Parkinson's Disease Therapy or as a result of PD Therapy (End of Dose "Wearing Off Effect")

Aranesp and Epoetin Alfa Prior Auth Criteria:

CIGNA HealthCare covers hematopoietic growth factors (epoetin alfa [Epogen®, Procrit®] or

darbepoetin alfa [Aranesp®]) as medically necessary when ANY of the following indications are

met:

 anemia associated with chronic kidney disease, including patients who are predialysis or on

dialysis

- anemia associated with cancer chemotherapy
- anemia in patients with HIV infection who are receiving zidovudine therapy (epoetin only)
- reduction of allogeneic blood transfusions in surgery patients (epoetin only)
- anemia in chronic diseases, including:

myelodysplastic syndrome

lymphoproliferative disorders

anemia due to ribavirin use in patients infected with hepatitis C

cancer patients who are not treated with chemotherapy but have anemia associated with ANYof the following:

o prior chemotherapy

o prior radiation therapy

o current treatment with radiation therapy

o malignancy

CIGNA HealthCare does not cover hematopoietic growth factors (epoetin alfa [Epogen®, Procrit®]

or darbepoetin alfa (Aranesp®]) for the following indications, because it is considered experimental, investigational or unproven (this list may not be all-inclusive):

- pruritis (uremic)
- patients requiring immediate correction of severe anemia
- anemia in patients with rheumatoid arthritis
- anemia of prematurity
- · anemia in women with postpartum iron deficiency anemia
- anemia in patients with congestive heart failure
- sickle-cell anemia in patients who do not respond to hydroxyurea

Arava Prior Auth Criteria:

CIGNA Pharmacy Management covers Arava as medically necessary when all of the following indications are met:

- Diagnosis of rheumatoid arthritis
- Prior failure, contraindication, or intolerance of two formulary Disease Modifying Anti-Rheumatic drugs:
 - o azathioprine
 - o hydroxychloroquine
 - methotrexate
 - o Ridaura
 - o sulfasalazine
- Methotrexate monotherapy has been tried and failed

Aredia Prior Auth Criteria:

Pamidronate Disodium (Aredia®) may be covered as part of the management of members

when medical necessity has been established. Coverage for Pamidronate Disodium (Aredia®) may be provided without further review when the request establishes the following:

- For the treatment of Hypercalcemia of malignancy (HCM).
- For the treatment of osteolytic bone metastases of breast cancer or osteolytic lesions of multiple myeloma -- to be used in conjunction with standard antineoplastic therapy. Treatment of moderate to severe Paget disease in patients who failed to respond, or no longer respond to other treatments such as alendronate, risedronate, tiludronate, oral etidronate.

The following are generally considered to be experimental/investigational or unproven uses of

Pamidronate Disodium (Aredia®):

• For the treatment of hypercalcemia associated with hyperparathyroidism or other nontumor-related conditions.

Atgam Prior Auth Criteria:

CIGNA Pharmacy Management covers Antithymocyte Globulin (Atgam™) as medically necessary when the following indications are met:

- Management of allograft rejection in renal transplant patients
- Treatment of moderate-to-severe aplastic anemia
- Use as an immunosuppressant in liver, bone-marrow, heart, skin, and other organ transplants

CIGNA Pharmacy Management does not cover Antithymocyte Globulin (Atgam™) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

• Treatment of patients with multiple sclerosis, myasthenia gravis, pure red-cell aplasia, or scleroderma.

Botox Prior Auth Criteria:

CIGNA HealthCare covers botulinum toxin type A (Botox® A) as medically necessary the following

indications are met:

- 1. Dystonias, Spasticities, and Neuro-opthalmological conditions, including: Focal Dystonias
- treatment of blepharospasm;
- cervical dystonia, including spasmodic torticollis, causing persistent pain or interfering with the patient's ability to perform age-related activities of daily living
- focal hand dystonia (e.g., writer's cramp) causing persistent pain or interfering with the patient's ability to perform age-related activities of daily living
- adductor spasmodic dysphonia/laryngeal dystonia when the condition is interfering with the patient's ability to communicate effectively
- jaw-closing oromandibular dystonia causing any one of the following: persistent pain, interference with nutritional intake (e.g., masticatory dysfunction that results in weight loss or malnutrition), or significant speech impairment/interference with the ability to communicate effectively
- Meige's syndrome/cranial dystonia (i.e., blepharospasm with jaw-closing oromandibular cervical dystonia), when jaw-closing oromandibular dystonia is causing any one of the following: persistent pain, interference with nutritional, or significant speech impairment/interference with the ability to communicate effectively.

Spastic conditions

- cerebral palsy (including spastic equinus foot deformities)
- cerebrovascular accident
- localized adductor muscle spasticity in multiple sclerosis
- spinal cord injury
- traumatic brain injury

Hemifacial spasms/Seventh cranial nerve palsy causing persistent pain or vision impairment.

Strabismus disorders in adults, in situations when:

- (a) One of the following is present:
- Horizontal strabismus up to 50 prism diopters
- Vertical strabismus
- Persistent sixth nerve palsy of one month or longer duration

AND

- (b) One the following is present:
- Diplopia;
- Impaired depth perception;
- Impaired peripheral vision;
- Impaired ability to maintain fusion.

Strabismus disorders in children, to achieve normal binocular motor alignment.

2. Gastrointestonal Conditions, including:

Primary Esophogeal Achalasia:

 Patients who are considered poor surgical risks (e.g., patients with comorbidities such as elderly patients with decreased life expectancy);
 OR

• Patients who have a history of perforation caused by previous pneumatic

dilatation.

Chronic anal fissure, in patients who have failed conventional nonsurgical treatment (e.g., nitrate preparations, sitz baths, stool softeners, bulk agents, diet modifications) 3. Hyperhidrosis:

For the treatment of primary and secondary axillary or palmar hyperhidrosis or gustatory sweating (Frey's syndrome) and the following:

- When the condition is refractory to conventional medical treatment, including an attempt at both topical and pharmacotherapy (unless clinically contraindicated); and either (1) or (2):
- 1. The condition is significantly interfering with the patient's ability to perform age-appropriate activities of daily living; OR
- 2. The condition is causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections and secondary microbial conditions.
- 4. Voiding dysfunction associated with any of the following: intracranial lesions or cerebrovascular accident-induced voiding difficulty detrusor sphincter dyssynergia due to spinal cord injury

CIGNA HealthCare does not cover for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

chronic pain including: low back pain, mastectomy reconstruction pain, hemorrhoid pain,

myofascial pain, chronic prostate pain, tennis elbow, chronic neck pain

temporo-mandibular dysfunction or chronic orofacial pain

headache (tension-type headache, chronic daily headache)

migraine

rhinitis

tics

paralytic scoliosis

diabetic gastroparesis

sphincter of Oddi dysfunction

Voiding dysfunction associated with any of the following:

- benign prostatic hyperplasia
- detrusor hyperreflexia due to myelomeningocele
- urge incontinence refractory to anticholinergic therapy treatment of sialorrhea including:
- · Parkinson's Disease sialorrhea
- Cerebral Palsy sialorrhea

Byetta Prior Auth Criteria:

CIGNA Pharmacy Management covers exanatide (Byetta®) when ALL of the following medical necessity criteria are met:

- Use as adjunctive therapy in type II diabetes and
- Failure, contraindication or intolerance to metformin or sulfonylureas (such as glyburide or glipizide)

Cancidas Prior Auth Criteria:

CIGNA Pharmacy Management covers capsofungin (Cancidas™) as medically necessary when the following indications are met:

- Aspergillosis, invasive (treatment) in patients who are refractory to or intolerant of other therapies, including amphotericin B (lipid and non-lipid formulations) and/or itraconazole
- o Candidiasis, disseminated (treatment) or
- o Candidiasis, esophageal (treatment) or
- o Candidiasis, intra-abdominal abscesses (treatment) or
- o Candidiasis, peritonitis (treatment) or
- Candidiasis, pleural space infections (treatment)
- o Fungal infection, presumed, in febrile neutropenia (treatment)

CIGNA Pharmacy Management does not cover capsofungin (Cancidas™) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

as initial therapy for invasive aspergillosis

Carnitor Prior Auth Criteria:

CIGNA Pharmacy Management covers Levocarnitine (Carnitor®) when ALL of the following medical necessity criteria are met:

- Carnitine deficiency (treatment
- for the treatment of secondary carnitine deficiency resulting from an inborn error of metabolism.
- Carnitine deficiency, in end-stage renal disease (ESRD) patients on hemodialysis (prevention and treatment)
- Carnitine deficiency, secondary to valproic acid toxicity (prophylaxis and treatment

Celebrex Prior Auth Criteria:

CIGNA Pharmacy Management covers celecoxib (Celebrex®) when ALL of the following medical necessity criteria are met:

• Failure, contraindication or intolerance to 4 generic NSAIDs

Cerezyme Prior Auth Criteria:

CIGNA Pharmacy Management covers Imiglucerase (Cerezyme®) when ALL of the following medical necessity criteria are met:

- Adult (age 18 or greater)
- Treatment of type 1 Gaucher's Disease
- Monotherapy use only

Chelation Therapy Prior Auth Criteria:

Common Indications:

Based on peer reviewed literature, there is sufficient evidence to support the use Chelation

Therapy (Chelating agents) in the following indications:

- 1. For lead overload/poisoning in one of the following:
- (Typical treatment agents: Calcium Disodium Versenate; BAL in Oil®; Chemet®)
 - (a) Pediatric patients (less than 18 years of age) with blood lead levels of 25 μ g/dL* or greater;
 - (b) Adult patients (18 years of age or older) with blood lead levels greater than 70 $\mu g/dL^*$ with or without symptoms of toxicity or adults with blood lead levels greater than 50 $\mu g/dL$ who are exhibiting moderate to severe symptoms of lead toxicity.
 - CaNa2EDTA and Dimercaprol (BAL®, or British Anti Lewisite, in Oil-AKORN) constitute the standard of care for treatment of lead intoxication.
 - Typically, dimercaprol is reserved for more severe cases (patients with blood lead levels of greater than 70 µg/dL or with lead encephalopathy).
 - Dosing with Edetate Calcium may be as follows:
 - For blood lead levels 20 to 70 mcg/dL, the recommended dose for asymptomatic adults and pediatric patients whose blood lead level is less than 70 mcg/dL is 1000 mg/m2/day whether given IV or IM.
 - Therapy is continued over a period of 5 days. Therapy is then interrupted for 2 to 4 days and depending upon the severity of the lead toxicity and the patient's tolerance of the drug, a second course of treatment is usually employed.
 - For blood lead levels more than 70 mcg/dL, it is recommended that calcium EDTA be used in conjunction with dimercaprol. Therapy is initiated with an IM dose of dimercaprol, another IM dose of dimercaprol 4 hours later, followed immediately by IV Calcium EDTA as a single dose infused over several hours or as a continuous infusion.
 - Oral succimer (DMSA or CHEMET®) is also currently FDA approved only for blood lead levels greater than 45 $\mu g/dL$.
- 2. Patients with chronic iron overload due to transfusion-dependent anemias (e.g., thalassemias, Cooley's anemia, sickle cell anemia), or secondary hemochromatosis (*Typical treatment agent: Desferal*®)
 - Deserferal route of administration for chronic iron overload may be IM or SC.
 - IM doing is as follows: 500 mg to 1 g/day. Give 2 g IV with, but separate from, each unit of blood. The rate of IV infusion must not exceed 15 mg/kg/h. The total daily dose should not exceed 1 g in the absence of a transfusion, or 6 g even if transfused 3 or more units of blood or packed red blood cells.
 - SC dosing is as follows: 1 to 2 g/day (20 to 40 mg/kg/day) over 8 to 24 hours with continuous mini-infusion pump. Individualize infusion duration. In some patients, iron excretion will be as much after a short infusion (8 to 12hours)as if the same dose is given over 24 hours.
 - Children: Maximum dose is 6 g/24 h.

or

- 3. Patients with copper overload/toxicity secondary to Wilson's disease. (Typical treatment agent: Syprine \circledR)
 - Typical dosing is as follows:
 For adults initially treat with 750 to 1250 mg/day in divided doses 2, 3, or 4times/day. May increase to a maximum of 2000 mg/day.

 For children 12 years of age and under initially treat with 500 to 750 mg/day in divided doses 2, 3, or 4 times/day. May increase to a maximum of 1500 mg/day.
 - Increase the daily dose only when the clinical response is not adequate or the concentration of free serum copper is persistently above 20 mcg/dL. Determine optimal long-term maintenance dosage at 6-to 12-month intervals.

or

- 4. Patients with arsenic, mercury, iron, copper or gold poisoning:
- (a) When there is a history consistent with exposure (such as observed ingestion); and (b) Toxicity has been confirmed through the appropriate lab results (i.e., blood, plasma, and/or urine results) or clinical findings (i.e., symptoms consistent with metal toxicity).

The following indications and uses do not have sufficient evidence to support the use of Chelating Agents:

Coronary Artery Disease or Myocardial Infarction with ischemic symptoms

Compounded Drug Therapies Prior Auth Criteria:

A compounded prescription medication is a mixture of two or more pharmaceutical ingredients where at least one of the ingredients in the preparation is a Federal or State legend drug in a therapeutic amount. The preparation of intravenous admixtures is not considered a compounded prescription medication, nor is the reconstitution of oral suspensions and similar products.

CIGNA Pharmacy Management covers Compounded Drug Therapies when the following medical necessity criteria are met:

- For their use in accord with the FDA labeled indications of the therapeutic ingredient(s) or acceptable off-label indications where
 - compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs will be either excluded or classified as experimental or investigation if prepared in accordance with an FDA sanctioned investigational new drug application.
 - ii) compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products must have documented medical need for a particular variation of the compound for a particular patient.

Copaxone Prior Auth Criteria:

CIGNA Pharmacy Management covers Glatiramer Acetate (Copaxone®) when the following medical necessity criteria are met:

- Diagnosis of clinically definite Multiple Sclerosis or,
- Diagnosis of Relapsing Remitting Multiple Sclerosis (RRMS)

CytoGam Prior Auth Criteria:

CIGNA Pharmacy Management covers Cytomegalovirus Immune Globulin IV (CytoGam™) as medically necessary when the following indications are met:

- For CMV prophylaxis in patients undergoing kidney, lung, pancreas, heart or other solid organ transplantation (usually in conjunction with other antiviral therapy) or,
- For CMV prophylaxis in patients undergoing allogenic bone marrow transplant or,
- For the treatment of CMV Pneumonitis in Transplant Recipients

CIGNA Pharmacy Management does not cover Cytomegalovirus Immune Globulin IV (CytoGam™) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

For the prevention or treatment of CMV disease in patients with HIV For the prevention or treatment of CMV disease in premature neonates

Enbrel Prior Auth Criteria:

CIGNA HealthCare covers etanercept (Enbrel.) as medically necessary when the following indications are met:

 treatment of rheumatoid arthritis (RA) and when ANY of the following indications are met:

history of positive clinical response to etanercept therapy with progression of disease as manifested by uncontrolled synovitis and either increased morning stiffness (i.e., greater than or equal to 45 minutes in duration), erythrocyte sedimentation rate (ESR) > 28, or C-reactive protein (CRP) > 2 AND

failure, contraindication, or intolerance to methotrexate therapy

 treatment of chronic plaque psoriasis and when ALL of the following indications are met:

patients who are candidates for phototherapy (narrow and broad band ultraviolet B [UVB],

psoralen + ultraviolet A [PUVA]) or systemic therapy (e.g. methotrexate, cyclosporin,

soriatane)

age 18 or older

at least 10% body surface area (BSA) affected

previous use of topical therapies, such as corticosteroids, Tazorac, Dovonex, anthralin,

salicylic acids, or tars for six months

 treatment of inflammatory bowel disease arthritis and when ANY of the following indications are met:

history of positive clinical response to etanercept therapy

failure, contraindication, or intolerance to sulfasalazine, azathioprine, steroids,

methotrexate

 treatment of ankylosing spondylitis and when ANY of the following indications are met: •

history of positive clinical response to etanercept therapy failure, contraindication, or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs)

• for treatment of ANY of the following indications:

polyarticular-course juvenile rheumatoid arthritis psoriatic arthritis

reactive arthritis

AND when ANY of the following indications are met: history of positive clinical response to etanercept therapy failure, contraindication, or intolerance to methotrexate therapy

Note: For chronic plaque psoriasis, the initial approval limits will be three months with the ability to increase to twelve-month intervals, providing therapeutic response was achieved. There is no limited authorization for patients who are diagnosed with rheumatoid arthritis (RA), polyarticularcourse juvenile rheumatoid arthritis, ankylosing spondylitis, reactive arthritis, or inflammatory bowel disease arthritis and who have a history of positive clinical response.

CIGNA HealthCare does not cover etanercept (Enbrel.) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- patient who has already received high dose therapy (50 mg twice weekly) for chronic plaque psoriasis
- doses higher than 50 mg per week for the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis

Flolan Prior Auth Criteria:

CIGNA HealthCare covers epoprostenol (Flolan™) when ALL of the following medical necessity criteria are met:

- treatment of primary pulmonary hypertension
- patients with New York Heart Association (NYHA) Class III and Class IV
 failure, contraindication, intolerance to oral therapy, bosentan (Tracleer)

Forteo Prior Auth Criteria:

CIGNA Pharmacy Management covers Teriparatide (Forteo®) when the following medical necessity criteria are met:

- Treatment of osteoporosis in postmenopausal women who are at high risk for having a fracture or,_
- Use is to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture and,
- Evidence of adequate trial or documented failure, intolerance, or contraindication to one formulary alternative

Gleevec Prior Auth Criteria

CIGNA Pharmacy Management covers Imitinib (Gleevec®) when the following medical necessity criteria are met:

In Adult Patients:

- Diagnosis of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in one of the following phases:
- · CML myeloid blast crisis or,
- · CML accelerated phase or,
- CML in chronic phase after failure of interferon treatment or hydroxyurea treatment or,
- Initial therapy in newly diagnosed patients or,
- Recurrence of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) following stem cell transplantation (SCT) or,
- For a diagnosis of metastatic gastrointestinal stromal tumor (GIST)

In Pediatric Patients:

- Diagnosis of Philadelphia chromosome positive(Ph+) chronic myeloid leukemia (CML) in chronic phase and one of the following:
 - o Disease has recurred after stem cell transplant; or
 - o There has been documented resistance to interferon alpha therapy

Granulocyte Colony Stimulating Factor Therapy Prior Auth Criteria:

Granulocyte Colony stimulating Factor Therapy includes the following drugs:

- Filgrastim (Neupogen.)
- Pegfilgrastim (Neulasta.)

CIGNA Pharmacy Management covers Granulocyte Colony stimulating Factor Therapy when the following

medical necessity criteria are met:

For Neupogen or Neulasta:

- Primary administration for patients considered at high risk of febrile neutropenia (FN) due to special circumstances, including, but not limited to, the following risk factor circumstances: preexisting neutropenia due to disease, extensive prior chemotherapy; or previous irradiation to the pelvis or other areas containing large amounts of bone marrow; a history of recurrent febrile neutropenia while receiving earlier chemotherapy of similar or lesser dose-intensity; or conditions potentially enhancing the risk of serious infection, e.g., decreased immune function, open wounds, or already active tissue infections
- Secondary administration, when there has been previous documentation of febrile neutropenia after chemotherapy, for patients whom are not candidates for chemotherapy dose reduction as an alternative means of preventing febrile neutropenia, or when prolonged neutropenia is creating delay in chemotherapy treatment
- For use with antibiotics in febrile, neutropenic patients identified as having high risk prognostic factors that are predictive of clinical deterioration, such as pneumonia, hypotension, multi-organ dysfunction (sepsis syndrome), or fungal infection
- For mobilizing peripheral blood progenitor cells (PBPCs) for transplantation
- For patients with myelodyplastic syndrome (MDS), identified as having severe neutropenia and recurrent infection, and are in need of intermittent CSF administration

For Neupogen Only:

- Cancer patients receiving bone marrow transplant (BMT)
- Patients undergoing peripheral blood progenitor (PBPC) cell collection and/or therapy
- Patients evaluated to be symptomatic w/ congenital, cyclic or idiopathic neutropenia
- HIV and/or AIDs associated neutropenia secondary to the disease itself, infection with opportunistic organisms, or antiretroviral agents
- Patients evaluated as needing an increase in neutrophil count due to a primary diagnosis including: Aplastic anemia, Hairy cell leukemia, Myelodysplasia, drug induced and congenital agranulocytosis, or Alloimmune Neonatalneutropenia

Growth Hormone Prior Auth Criteria:

Recombinant Human Growth Hormone Therapy includes the following drugs:

- Somatropin (Humatrope®) preferred brand
- Somatropin (Nutropin®) preferred brand
- Somatrem (Protropin®) preferred brand
- Somatropin (Genotropin®)
- Somatropin (Norditropin®)
- Somatropin (Saizen®)
- Somatropin (Serostim®)

CIGNA Pharmacy Management covers Recombinant Human Growth Hormone Therapy when the following medical necessity criteria are met:

Growth Hormone Use in Children

- For Growth Hormone Deficiency in Children (including pituitary dwarfism as well as growth hormone deficiency following cranial irradiation), where:
 - o Patient must be evaluated by an endocrinologist. And
 - Growth hormone response of less than 10ng/ml to at least two provocative stimuli of growth hormone release: Insulin, Levodopa, L-Arginine, Clonidine, Glucagon. and
 - (The preferred stimuli test is Insulin, with the secondary preferred as L-Arginine)
 - Patient's height is more than 2 SD below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age, or for children over 2 yrs of age, a decrease in height SD of more than 0.5 over 1 year. and
 - o Patient must be followed annually by an endocrinologist.

Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required. Coverage will cease when the bony epiphyses have closed.

or

• For Growth Delay in Children with Chronic Renal Failure:

Reauthorization of coverage for the above indication is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required. Coverage will cease at the bony epiphyses have closed.

or

- For Turner Syndrome, where:
 - o Patient must be evaluated by an endocrinologist. and
 - Documentation of diagnosis as has been established by genetic testing.
 and

- Patient's height is more than 2 SD below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age, or for children over 2 yrs of age, a decrease in height SD of more than 0.5 over 1 year. and
- patient must be followed annually by an endocrinologist.

Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required. Coverage will cease when the bony epiphyses have closed.

or

- For Prader-Willi Syndrome, where:
 - o Patient must be evaluated by an endocrinologist.
 - o Patient must be followed annually by an endocrinologist.

or

Russell-Silver Syndrome

or

- Small for Gestational Age (Intrauterine Growth Retardation and related SGA syndromes), where:
 - Patient must be evaluated by an endocrinologist. and
 - o Patient must be followed annually by an endocrinologist. and
 - o Patient must be at least 2 years old to have diagnosis made of SGA

These children have intrauterine growth retardation (IUGR) that results in short stature because of a specific congenital anomaly such as IGF-I deficiency or maternal factors such as diabetes, infections, hypoxia, addictions, or placental dysfunction

Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required. Coverage will cease when the bony epiphyses have closed.

or

Growth Hormone Use in Adults:

- Growth Hormone Deficiency in Adults, where:
 - o Patient must be evaluated by an endocrinologist. and
 - o Etiology of Growth Hormone Deficiency (GHD) has been identified as:
 - Adult Onset Growth Hormone Deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism, as a result of hypothalamic or pituitary disease, radiation therapy, surgery, or trauma. and
 - GHD has been confirmed by growth hormone stimulation tests and ruleout of other hormonal deficiency, as follows:
 - Growth hormone response of less than 5 nanograms per mL to at least two provocative stimuli of growth hormone release: Insulin, Levodopa, L-Arginine, Clonidine or Glucagon when measured by

- polyclonal antibody (RIA) or less than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA) and *(The preferred stimuli test is Insulin, with the secondary preferred as L-Arginine)*
- Rule-out and appropriate correction for other hormonal deficiencies such as thyroid, cortisol or sex steroids. or
- Stimulation testing would not produce a clinical response such as in a diagnosis of pan-hypopituitarism as defined by the absence of all anterior pituitary hormones [Lutenizing Hormone, (LH), Follicle Stimulating Hormone, (FSH), Thyroid Stimulating Hormone, (TSH), Adrenocorticotropic Hormone, (ACTH) and Growth Hormone, (GH).

or

- Treatment of AIDS Wasting, where
 - There has been documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents.

or

- Treatment of Short Bowel Syndrome, where
 - Used with special diets and glutamine supplementation.

CIGNA Pharmacy Management does not cover Recombinant Human Growth Hormone Therapy because it is considered not medically necessary or of unproven benefit or cosmetic for the following diagnoses (this list may not be all-inclusive):

Growth Hormone Use in Children

- Constitutional Delay of Growth and Development
- Skeletal Dysplasias
- Osteogenesis Imperfecta
- Down Syndrome and Other Syndromes Associated With Short Stature and Malignant Diathesis
- Continuation of growth hormone treatment once epiphyses are closed.
- Idiopathic (of unknown origin) Short Stature, also called non-growth hormone deficient short stature.

Growth Hormone Use in Adults

- Continuation of GH treatment once epiphyses are closed (except as defined in Adult GH coverage conditions).
- Obesity,
- Osteoporosis,
- Muscular Dystrophy,
- Infertility,
- Increased athletic performance
- "Somatopause"

Histrelin Prior Auth Criteria:

CIGNA HealthCare covers histrelin (Vantas™) as medically necessary when the following indication is met:

• advanced prostate cancer

CIGNA HealthCare does not cover histrelin (Vantas™) for the following indication because it is considered experimental, investigational or unproven (this list may not be all inclusive):

central precocious puberty

Humira Prior Auth Criteria:

CIGNA HealthCare covers adalimumab (Humira.) as medically necessary when the following indications are met:

treatment of rheumatoid arthritis (RA) and when ANY of the following indications are met:

- history of positive clinical response to adalimumab therapy
- documented progression of disease as manifested by uncontrolled synovitis and either increased morning stiffness (greater than or equal to 45 minutes in duration), erythrocyte sedimentation rate (ESR) > 28, or Creactive protein (CRP) > 2 AND
- failure, contraindication, or intolerance to methotrexate therapy

treatment of psoriatic arthritis AND when ANY of the following indications are met:

- history of positive clinical response to adalimumab therapy
- failure, contraindication, or intolerance to methotrexate therapy

Note: No limited authorization for patients who are diagnosed with rheumatoid arthritis (RA) or psoriatic arthritis and have a history of positive clinical response.

CIGNA HealthCare does not cover adalimumab (Humira.) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- treatment of ankylosing spondylitis
- treatment of plaque psoriasis

IGIM Prior Auth Criteria:

CIGNA HealthCare covers immune globulin (human) intramuscular (BayGam®) as medically necessary when ANY of the following indications are met:

- prophylactic treatment for hepatitis A when given before or soon after exposure to hepatitis A
- prevent or modify measles in a susceptible person exposed fewer than six days. A susceptible

person is:

- one who has not been vaccinated and has not had measles previously
- household contacts of measles patients, particularly contacts under one year of age
- immunocompromised patients
- prophylaxis of rubella in women who have been exposed to rubella in the first trimester of pregnancy
- passive immunization against varicella in immunosuppressed patients when Varicella-Zoster

immune globulin (human) is not available

• immunoglobulin deficiency prevent serious infection if circulating IgG levels of ~200 mg/dl plasma are maintained prophylactic therapy against infection in Bruton-type, sex-linked, congenital agammaglobulinemia, agammaglobulinemia associated with thymoma, and acquired agammaglobulinemia

CIGNA HealthCare does not cover immune globulin (human) intramuscular (BayGam®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- in persons with clinical manifestations of hepatitis A or in those exposed more than two weeks previously
- prevent chronic infections of the external secretory tissues such as the respiratory and gastrointestinal tract
- routine prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella
- for allergy or asthma in patients who have normal levels of immunoglobulin

Increlex™ Prior Auth Criteria:

CIGNA HealthCare covers mecasermin (Increlex®) as medically necessary when ANY of the following indications are met:

• treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1)

deficiency, OR with growth hormone (GH) gene deletion who have developed neutralizing

antibodies to GH

AND when ALL of the following indications are met:

o patient's height is equal or more than three standard deviations (SD) below normal

o basal IGF-1 level is below normal per lab value

o normal or elevated growth hormone (GH)

CIGNA HealthCare does not cover mecasermin (Increlex®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

for treatment of secondary forms of IGF-1 deficiency due to ANY of the following:
 GH deficiency

malnutrition

hypothyroidism

chronic treatment with pharmacologic doses of anti-inflammatory drugs

Note: Severe primary IGF-1 deficiency includes patients with mutations in the GH receptor (GHR), post-

GHR signaling pathway, and IGF-1 gene defects.

Infergen Prior Auth Criteria:

CIGNA HealthCare covers interferon alfacon-1 (Infergen®) as medically necessary when ALL of the following indications are met:

- treatment of chronic hepatitis C virus (HCV) infection
- 18 years of age or older
- patients with compensated liver disease who have anti-HCV serum antibodies and/or the presence of HCV RNA

Note: Coverage of interferon alfacon-1 (Infergen®) can be approved for 48 weeks.

CIGNA HealthCare does not cover interferon alfacon-1 (Infergen®) for the following indication, because it is considered not medically necessary or of unproven benefit (this list may not be allinclusive):

treatment beyond 48 weeks

Iplex™ Prior Auth Criteria:

CIGNA HealthCare covers mecasermin rinfabate (Iplex®) as medically necessary when the following indications are met:

• treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1)

deficiency OR with growth hormone (GH) gene deletion who have developed neutralizing

antibodies to GH

AND when ALL of the following indications are met:

- o Patient's height is equal or more than 3 standard deviations (SD) below normal.
- o Basal IGF-1 level is below normal per lab value.
- o Patient has normal or elevated growth hormone (GH).

CIGNA HealthCare does not cover mecasermin rinfabate (Iplex®) because it is considered experimental, investigational or unproven for (this list may not be all inclusive):

treatment of secondary forms of IGF-1 deficiency due to ANY of the followings:
 GH deficiency

GH delicienc

malnutrition

hypothyroidism

chronic treatment with pharmacologic doses of anti-inflammatory

Note: Severe primary IGF-1 deficiency includes patients with mutations in the GH receptor (GHR), post-

GHR signaling pathway, and IGF-1 gene defects.

Injectable Drugs, Not Otherwise Specified Prior Auth Criteria:

Absent any applicable exclusion, CIGNA Pharmacy Management covers injectable medications with criteria not otherwise specified when the following medical necessity criteria are met:

- when used for the accepted, FDA Approved indications or
- for accepted off-label indications as further defined by:
 - The drug has not been contraindicated by the FDA for the off-label use prescribed. and
 - The drug must be approved by the FDA and must have been proven safe, effective and accepted for the treatment of the specific medical condition for which the drug has been prescribed, as evidenced by supporting documentation in any one of the following:
 - The American Hospital Formulary Service Drug Information or The United States Pharmacopoeia Drug Information or DRUGDEX Information System.

Iressa Prior Auth Criteria:

CIGNA Pharmacy Management covers Gefitinib (Iressa®) when the following medical necessity criteria are met:

• For use as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies

IVIG Prior Auth Criteria:

CIGNA HealthCare covers immune globulin intravenous (human) (IGIV) as medically necessary when ANY of the following indications are met:

• treatment of primary immunodeficiency syndrome, such as:

congenital / X-linked agammaglobulinemia

hypogammaglobulinemia

common variable immunodeficiency

X-linked immunodeficiency with hyperimmunoglobulin M

severe combined immunodeficiency

Wiskott-Aldrich syndrome

- treatment of idiopathic thrombocytopenic purpura
- treatment of Kawasaki disease in conjunction with aspirin within ten days of onset of symptoms
- prevention of recurrent bacterial infections in patients with hypogammaglobulinemia associated

with B-cell chronic lymphocytic leukemia (CLL)

• prevention of the risk of infection in bone marrow transplantation (BMT) in recipients who are age

20 or older in the first 100 days after transplantation

 prevention of mild to severe bacterial infections in ANY of the following: human immunodeficiency virus (HIV)-infected children with CD4+ counts > 200/μl, when

used in conjunction with zidovudine or other antiretroviral treatment

HIV-positive children and adolescents who either have been exposed to measles or live in a

high-prevalence measles area

maternal-fetal transmission of HIV in women who are in their third trimester of pregnancy,

when used in conjunction with zidovudine or other antiretroviral treatment

 treatment of dermatomyositis or polymyositis in patients who have failed standard medical

therapy (e.g., corticosteroids and/or immunosuppressants) or when steroids are contraindicated

• treatment of Guillain-Barré syndrome (i.e., acute inflammatory demyelinating polyneuropathy

(AIDP) and chronic inflammatory demyelinating polyneuropathy (CIDP)

- treatment of hyperimmunoglobulinemia E syndrome
- treatment of Lambert-Eaton myasthenic syndrome (LEMS)
- treatment of multifocal motor neuropathy (MMN) in patients who have failed standard medical

therapy

• treatment of relapsing-remitting multiple sclerosis (MS) in patients who have failed standard

medical therapy (e.g., interferon beta-1a, interferon beta-1b)

prevention of, and as a treatment adjunct in, infections in some high-risk, preterm, low-birthweight

neonates

• treatment of chronic parvovirus B19 infection and severe anemia associated with bone marrow

suppression

- treatment of neonatal isoimmune hemolytic disease in conjunction with phototherapy
- use in allosensitized solid organ transplants
- · prevention of infection in patients with multiple myeloma

CIGNA HealthCare does not cover immune globulin intravenous (human) (IGIV) for the following indications because it is considered experimental, investigational or unproven:

- amyotrophic lateral sclerosis
- intractable pediatric epilepsy
- myasthenia gravis
- stiff person syndrome
- autoimmune neutropenia
- fetal alloimmune thrombocytopenia
- immune mediated blistering diseases including ANY of the following: pemphigus paraneoplastic pemphigus pemphigoid linear IgA bullous disease cicatricial pemphigoid epidermolysis bullosa acquisita Stevens-Johnson syndrome (bullous erythema multiforme) toxic epidermal necrolysis
- recurrent spontaneous miscarriage
- toxic shock syndrome

Kineret Prior Auth Criteria:

CIGNA Pharmacy Management covers anakinra (Kineret) when all of the following medical necessity criteria are met:

Note: Initial approval limits will be three months with the ability to increase to twelve month intervals, providing therapeutic response was achieved.

- Treatment of rheumatoid arthritis (RA) with progression of disease as manifested by uncontrolled synovitis and either increased morning stiffness (greater than or equal to 45 minutes in duration), erythrocyte sedimentation rate (ESR) >28, or C-reactive protein (CRP) >2
- Failure, contraindication or intolerance to methotrexate therapy

The recommended dose of anakinra is 100 mg/day administered daily by subcutaneous injection. Higher doses did not result in a higher response. Administer the dose at approximately the same time every day. Anakinra can be used alone or in combination with disease modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF)-blocking agents.

Leukine Prior Auth Criteria:

Sargramostim {Granulocyte Macrophage Colony Stimulating Factor, GM-CSF}, (Leukine)

may be covered as part of the management of members when medical necessity has been

established. Coverage for Sargramostim {Granulocyte Macrophage Colony Stimulating Factor, GM-CSF}, (Leukine) may be provided without further review when the request establishes the following:

- Myeloid reconstitution after autologous bone marrow transplantation (BMT) for patients diagnosed with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL), and Hodgkin's disease.
- Bone marrow transplantation failure (MBT) or engraftment delay for patients who have undergone allogeneic or autologous BMT.
- Mobilization and following transplantation of autologous peripheral blood progenitor cells (PBPC).
- Myeloid reconstitution after allogeneic BMT.
- Neutropenia associated with bone marrow transplant, graft failure, and delay of engraftment and for promotion of early engraftment. (*orphan indication per FDA*)

Patients evaluated as not being appropriate candidates for alternative therapy options, and

are evaluated as having a need for Sagromostim {GM-CSF} use due the following conditions:

Crohn's disease; melanoma; wound healing; mucositis; stomatitis; vaccine adjuvancy; myelodysplasia; aplastic anemia; drug-induced neutropenias; or congenital, cyclic, or acquired neutropenias. Following induction chemotherapy in acute myelogenous leukemia (AML) to shorten neutrophil recovery time and reduce the incidence of infections.

The beneficial effects of giving colony stimulating factors, in regard to specific endpoints, have not yet

been completely determined, necessitating caution in the use of these agents in the AML treatment setting.

Leuprolide Prior Auth Criteria:

CIGNA HealthCare covers leuprolide (Lupron®, Lupron Depot® 7.5 mg, 22.5 mg, and 30 mg,Eligard®, Viadur®) as medically necessary when the following indication is met:

advanced prostate cancer

CIGNA HealthCare covers leuprolide (Lupron Depot® 3.75 mg and 11.25 mg) as medically necessary when ANY of the following indications are met:

- uterine fibroids or leiomyomata (leuprolide therapy not to exceed three months for preoperative use)
- endometriosis
- AND

failure, contraindication or intolerance to a trial of oral contraceptives (leuprolide therapy not to exceed six months)

CIGNA HealthCare covers leuprolide (Lupron®, Lupron Depot-PED®) as medically necessary when the following indication is met:

central precocious puberty

CIGNA HealthCare does not cover leuprolide (Lupron®, Lupron Depot®, Lupron Depot-PED®, Eligard®, Viadur®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- · advanced breast cancer
- polycystic ovarian disease

Lyrica Prior Auth Criteria:

CIGNA Pharmacy Management covers pregabalin (Lyrica) as medically necessary when one of the following criteria is met:

- For Depression where there has been a failure of SSRI therapy OR
- For peripheral neuropathy where there has been a failure of tricyclic antidepressants or gabapentin or carbamazepine.

Mobic Prior Auth Criteria:

CIGNA Pharmacy Management covers meloxicam (Mobic®) when ALL of the following medical necessity criteria are met:

• Failure, contraindication or intolerance to 4 generic NSAIDs

Multiple Sclerosis Interferon Therapy Prior Auth Criteria:

Multiple Sclerosis Interferon Therapy includes the following drugs:

- Interferon beta-1a (Avonex®.)
- Interferon beta-1a (Rebif®)
- Interferon beta-1b (Betaseron®)

CIGNA Pharmacy Management covers Multiple Sclerosis Interferon Therapy when the following medical necessity criteria are met:

- Diagnosis of clinically definite Multiple Sclerosis or
- Diagnosis of Relapsing Remitting Multiple Sclerosis (RRMS) or
- Diagnosis of Secondary Progressive Multiple Sclerosis (SPMS) with relapses

Mycamine Prior Auth Criteria:

CIGNA Pharmacy Management covers Mycamine (Micafungin) when the following medical necessity criteria are met:

- Candidiasis, esophageal (treatment)
- Candidiasis, (prophylaxis).

Myobloc Prior Auth Criteria:

CIGNA HealthCare covers botulinum toxin type B (Myobloc®) as medically necessary when the following indication is met:

treatment of patients with cervical dystonia

CIGNA HealthCare does not cover botulinum toxin type B (Myobloc®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

• chronic pain including: low back pain, mastectomy reconstruction pain, hemorrhoid pain,

myofascial pain, chronic prostate pain, tennis elbow, chronic neck pain

- temporo-mandibular dysfunction or chronic orofacial pain
- headache (tension-type headache, chronic daily headache)
- migraine
- rhinitis
- tics
- · paralytic scoliosis
- · diabetic gastroparesis
- sphincter of Oddi dysfunction
- Voiding dysfunction associated with ANY of the following: benign prostatic hyperplasia detrusor hyperreflexia due to myelomeningocele urge incontinence refractory to anticholinergic therapy intracranial lesions or cerebrovascular accident-induced voiding difficulty detrusor sphincter dyssynergia due to spinal cord injury
- treatment of sialorrhea including: Parkinson's disease sialorrhea cerebral palsy sialorrhea

Neumega Prior Auth Criteria:

CIGNA Pharmacy Management covers Neumega when the following medical necessity criteria are met:

• For prophylaxis of Thrombocytopenia (TCP) following myelosuppressive chemotherapy

Nexavar® (sorafenib) Prior Auth Criteria:

CIGNA Pharmacy Management covers Nexavar® when the following medical necessity criteria are met:

• Treatment of Advance Renal Cell Carcinoma

Octreotide Prior Auth Criteria:

CIGNA HealthCare covers octreotide (Sandostatin®) as medically necessary when any of the following indications are met:

• for treatment of acromegaly in patients who have had inadequate response to or cannot be

treated with surgical resection, pituitary irradiation and bromocriptine mesylate at maximally

tolerated doses

• for symptomatic treatment of metastatic carcinoid tumors to suppress or inhibit the severe

diarrhea episodes associated with the disease

- for treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)
- to reduce the incidence and severity of the postoperative complications of high-risk pancreatic surgery
- with an appropriate adjunctive therapeutic intervention, such as sclerotherapy, to control bleeding and early rebleeding and to reduce transfusion requirements in patients with bleeding gastroesophageal varices associated with cirrhosis
- to reverse life-threatening hypotension due to carcinoid crisis during induction of anesthesia
- for palliative treatment of the symptoms resulting from hyperinsulinemia from severe refractory metastatic insulinoma
- for treatment of severe secretory diarrhea in AIDS patients who have failed to respond to antimicrobial or antimotility agents
- for treatment of chemotherapy-induced diarrhea

CIGNA HealthCare covers octreotide for injectable suspension (Sandostatin LAR® Depot) as medically necessary when BOTH of the following indications are met:

- long-term treatment of all indications listed above
- patients in whom initial treatment with Sandostatin injection has been shown to be effective and tolerated

CIGNA HealthCare does not cover octreotide (Sandostatin) or octreotide for injectable suspension (Sandostatin LAR Depot) for the following indication, because it is considered experimental, investigational or unproven (this list may not be all-inclusive):

· treatment of hepatocellular carcinoma

Onychomycosis Antifungal Therapy Prior Auth Criteria:

Onychomycosis Antifungal Therapy includes the following drugs:

- Terbinafine (Lamisil®)
- Itraconazole (Sporanox®)

CIGNA Pharmacy Management covers Onychomycosis Antifungal Therapy when the following medical necessity criteria are met:

For diagnosis of onychomycosis and one of the following below:

- Diabetes or
- Immunocompromised status due to disease (i.e. cancer, HIV / AIDS), organ or bone marrow transplant recipient,

or

For diagnosis of onychomycosis and the following conditions:

- Diagnosis has been confirmed by either a positive KOH stain, PAS stain, positive dermatophyte testing medium (DTM) or positive fungal culture and
- One of the following:
 - o Patient experiences pain limiting normal activity or
 - o Patient has significant peripheral vascular compromise and
- Oral onychomycosis therapy has not been used as treatment within the past 32 weeks

Coverage approval will extend to 12 weeks of therapy for toenail onychomycosis and 6 weeks for fingernail onychomycosis.

or

For diagnosis of non-systemic fungal infections (tinea pedis, tinea cruris, tinea versicolor, tinea capitis, and other cutaneous dermatophyte infections) and the following conditions:

• Failure, contraindication, or intolerance to ONE prescription topical antifungal therapy (e.g. Nizoral®, Loprox®, Naftin®, Spectazole®)

Coverage approval will extend to 4 weeks for tinea capitis and cutaneous dermatophyte infections and 2 weeks for tinea corporis infections.

or

For diagnosis of systemic fungal infections – Itraconazole (Sporanox®) only

Orencia Prior Auth Criteria:

CIGNA HealthCare covers abatacept (Orencia®) as medically necessary when ALL of the following indications are met:

- as monotherapy or concomitantly with methotrexate for the treatment of rheumatoid arthritis (RA)
- documented progression of disease manifested by uncontrolled synovitis and either increased morning stiffness (i.e., greater than or equal to 45 minutes in duration), erythrocyte

sedimentation rate (ESR) >28, or C-reactive protein (CRP) >2

AND when BOTH of the following indications are met:

- failure of methotrexate therapy alone
- failure/contraindication/intolerance to one formulary alternative tumor necrosis factor (TNF) antagonists (i.e., Enbrel®, Remicade®, Humira®)

CIGNA HealthCare does not cover abatacept (Orencia®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive).

- concomitant use with TNF antagonists for the treatment of RA
- · concomitant use with anakinra (Kineret®) for the treatment of RA

Panretin Prior Auth Criteria:

CIGNA Pharmacy Management covers Panretin when the following medical indications are met:

• Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma KS)

Pegylated Interferon Therapy Prior Auth Criteria:

Therapy includes the following drugs:

- Peginterferon alfa-2a (Pegasys®)
- Peginterferon alfa-2b (PEG Intron®)

CIGNA Pharmacy Management covers Pegylated Interferon Therapy when the following medical necessity criteria are met:

For Hepatitis C, with compensated liver disease, and the following conditions:

- Use of peginterferon alfa-2b or peginterferon alpha 2-a alone or in combination with ribavirin, USP (Rebetol® or Copegasus®) and
- No previous treatment with interferon alpha-2a; or
- Previous use of interferon alpha (Intron A®) and relapse has occurred; or
- Previous use of interferon alpha (Intron-A® and patient had to discontinue treatment due

to side effects

Coverage of either peginterferon alpha 2-b (PEG- Intron) or peginterferon alpha 2-a (Pegasys) can be approved for coverage for 48 weeks

CIGNA Pharmacy Management does not cover Pegylated Interferon Therapy because it is considered not medically necessary or of unproven benefit for the following diagnoses (this list may not be all-inclusive):

- Hepatitis C as diagnosis with following conditions:
 - Failure to respond to previous treatment with interferon alpha-2a, peginterferon alpha 2-a, or peginterferon alpha 2-b
 - Treatment beyond 48 weeks

Penlac Prior Auth Criteria:

CIGNA Pharmacy Management covers Penlac when the following medical necessity criteria are met:

For diagnosis of onychomycosis and one of the following below:

- Diabetes or
- Immunocompromised status due to disease (i.e. cancer, HIV / AIDS), organ or bone marrow transplant recipient,

or

For diagnosis of onychomycosis and the following conditions:

- Diagnosis has been confirmed by either a positive KOH stain, PAS stain, positive dermatophyte testing medium (DTM) or positive fungal culture and
- One of the following:
 - o Patient experiences pain limiting normal activity or
 - o Patient has significant peripheral vascular compromise and
- Oral onychomycosis therapy has not been used as treatment within the past 32 weeks

Plenaxis Prior Auth Criteria:

CIGNA Pharmacy Management covers Abarelix (Plenaxis®) when the following medical necessity criteria are met:

- Treatment of men with advanced symptomatic prostate cancer and
- Luteinizing hormone-releasing hormone (LHRH) agonist therapy is not appropriate
 or.
- Patients who refuse surgical castration and have one or more of the following:
 - o Risk of neurological compromise due to metastases or,
 - Ureteral or bladder outlet obstruction due to local encroachment or metastatic disease or.
 - o Severe bone pain from skeletal metastases persisting on narcotic analgesia

Proleukin Prior Auth Criteria:

CIGNA HealthCare covers aldesleukin (Proleukin®) as medically necessary when the following indications are met:

- restricted to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing AND when ANY of the following indications are met:
- treatment of adults with metastatic renal cell carcinoma (RCC)
- treatment of adults with metastatic melanoma
- treatment of human immunodeficiency virus (HIV)-infected patients and patients with leukemia

Provigil Prior Auth Criteria:

CIGNA Pharmacy Management covers modafinil (Provigil®) when ONE of the following medical necessity criteria is met:

 treatment of narcolepsy AND failure, contraindication, or intolerance to Ritalin or Dexedrine

-OR-

treatment of obstructive sleep apnea/hypopnea syndrome (OSAHS)

Raptiva Prior Auth Criteria:

CIGNA Pharmacy Management covers Efalizumab (Raptiva $^{\text{TM}}$) when all of the following medical necessity criteria are met:

- Adult patients (18 years or older)
- At least 10% Body Surface Area (BSA) affected
- Treatment of chronic, moderate to severe plaque psoriasis who are candidates for systemic therapy (Methotrexate, Cyclosporin, Soriatane) or phototherapy (Narrow and Broad Band UVB, PUVA)
 - Previous use of topical therapies, such as corticosteroids, Tazorac, Dovonex, anthralin, salicylic acids, tars for 6 months

Regranex Prior Auth Criteria:

CIGNA HealthCare covers becaplermin (Regranex®) as medically necessary when the following indications are met:

• use adjunctively with optimal wound care procedures that include initial sharp debridement,

infection control, and pressure relief for the treatment of lower extremity diabetic neuropathic

ulcers that extend into the subcutaneous tissue or beyond

CIGNA HealthCare does not cover for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- pressure ulcers
- venous stasis ulcers
- diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue

(Stage I or II, International Association Enterostomal Therapy (IAET) staging classification)

• ischemic diabetic ulcer

Remicade Prior Auth Criteria:

CIGNA HealthCare covers infliximab (Remicade.) as medically necessary when the following

indications are met:

- treatment of rheumatoid arthritis (RA) and when ANY of the following indications are met:
- history of positive clinical response to infliximab therapy
- failure, contraindication, or intolerance to methotrexate therapy
- treatment of chronic plaque psoriasis and when ALL of the following indications are met:
 - patients who are candidates for phototherapy (narrow and broad band ultraviolet B [UVB],
 - psoralen + ultraviolet A [PUVA]) or systemic therapy (i.e., methotrexate, cyclosporin,soriatane)
 - o age 18 or older
 - o at least 10% body surface area (BSA) affected
 - previous use of topical therapies, such as corticosteroids,
 Tazorac, Dovonex, anthralin,salicylic acids, tars for six months
- treatment of inflammatory bowel disease arthritis and when ANY of the following indications are met:
 - o history of positive clinical response to infliximab therapy
 - o failure, contraindication, or intolerance to sulfasalazine, azathioprine, steroids, or, methotrexate
- treatment of active Crohn's disease and when ANY of the following indications are met:
 - o history of positive clinical response to infliximab therapy
 - failure, inadequate response, contraindication or intolerance to conventional therapies (aminosalicylate, corticosteroids, or immunomodulators)
- re-treatment of fistulizing Crohn's disease with fistula present over at least three months in duration
- treatment of ulcerative colitis (UC) and when ANY of the following indications are met:
 - o history of positive clinical response to infliximab therapy
 - failure, inadequate response, contraindication or intolerance to conventional therapies: corticosteroids (e.g., prednisone, methylprednisolone), 5-aminosalicylic acid agents (e.g., sulfasalazine, mesalamine, balsalazide), immunosuppressants (e.g., azathioprine, cyclosporine, 6-mercaptopurine)
- treatment of ankylosing spondylitis and when ANY of the following indications are met:
 - o history of positive clinical response to infliximab therapy
 - failure, contraindication, or intolerance to non-steroidal antiinflammatory drugs (NSAIDs)
- for treatment of ANY of the following indications:
 - o psoriatic arthritis
 - o reactive arthritis
 - o AND when ANY of the following indications are met:

- o history of positive clinical response to infliximab therapy
- o failure, contraindication, or intolerance to methotrexate therapy

Note: For chronic plaque psoriasis, the initial approval limits will be three months with the ability to increase to twelve-month intervals, providing therapeutic response was achieved. There is no limited authorization for patients who are diagnosed with rheumatoid arthritis (RA), Crohn's disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis, reactive arthritis, or inflammatory bowel disease arthritis, and who have a history of positive clinical response.

CIGNA HealthCare does not cover for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

treatment of chronic obstructive pulmonary disease (COPD)

Remodulin Prior Auth Criteria:

CIGNA HealthCare covers treprostinil (Remodulin®) as medically necessary when ALL of the following indications are met:

- treatment of pulmonary arterial hypertension (PAH)
- patient with New York Heart Association (NYHA) Class II, III and IV
- failure, contraindication, intolerance to oral therapy, bosentan (Tracleer

Revatio Prior Auth Criteria:

CIGNA Pharmacy Management covers Sildenafil Citrate (Revatio™) when the following medical necessity criterion is met:

• Treatment of Pulmonary Arterial Hypertension

Revlimid Prior Auth Criteria:

CIGNA Pharmacy Management covers lenalidomide (Revlimid™) as medically necessary when the following indications are met:

 For the treatment of myelodysplastic syndromes (MDS) [MDS includes but is not limited to: Refractory Anemia (RA), Refractory Anemia with Ringed Sideroblasts (RARS), Refractory Anemia with Excess Blasts (RAEB), Refractory Anemia with Excess Blasts in Transformation (RAEB-t), Chronic Myelomonocytic Leukemia (CMML)]

Rituxan Prior Auth Criteria:

CIGNA HealthCare covers rituximab (Rituxan®) as medically necessary when ANY of the following indications are met:

- for treatment of non-Hodgkin's lymphoma
- for treatment of relapsed/refractory chronic lymphocytic leukemia
- for treatment of relapsed/refractory Waldenstrom's macroglobulinemia
- · for treatment of immune or idiopathic thrombocytopenic purpura
- in combination with methotrexate for the treatment of moderately to severely active rheumatoid arthritis in adults who have failed to respond adequately to one or more tumor

necrosis factor (TNF) antagonist therapies

CIGNA HealthCare does not cover rituximab (Rituxan®) for the following indications because it is considered experimental, investigational or unproven:

- for treatment of systemic lupus erythematosus (SLE)
- for treatment of primary progressive multiple sclerosis (PPMS)
- for treatment of lupus nephritis

Secreflo Prior Auth Criteria:

CIGNA Pharmacy Management covers Secretin (Secreflo™) as medically necessary when the following indications are met:

- Stimulation of pancreatic secretions to aid in pancreatic exocrine dysfunction or
- Stimulation of gastrin secretions to aid in the diagnosis of gastrinoma or
- Stimulation of pancreatic secretions during endoscopic retrograde cholangiopancreatography (ERCP)

Somavert Prior Auth Criteria:

CIGNA Pharmacy Management covers Pegvisomant (Somavert®) when the following medical necessity criteria are met:

For Acromegaly, where:

• Patients have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate.

Symlin Prior Auth Criteria:

CIGNA Pharmacy Management covers pramlintide (Symlin®) when ALL of the following medical necessity criteria are met:

- Use as adjunctive therapy in types I or II diabetes and
- Failure, contraindication or intolerance to metformin or sulfonylureas (such as glyburide or glipizide)

Synagis Prior Auth Criteria:

CIGNA HealthCare covers palivizumab (Synagis®) as medically necessary when the following indications are met:

• prophylaxis against lower respiratory tract infection with respiratory syncytial virus (RSV) with five to seven monthly doses (administration of the first dose at the beginning of October and the last dose at the beginning of April) of palivizumab (Synagis®) administration to infants and children under 24 months old in any of the following indications:

NOTE: See sections 5 and 6 below regarding number of doses covered.

1. Chronic Lung Disease

For infants or children under 24 months old, with Chronic Lung Disease (i.e. bronchpulmonary dysplasia) who have required medical care (supplemental oxygen, bronchodilator, diuretic, or corticosteroid therapy) for CLD within 6 months before the anticipated start of RSV season.

• Although there is limited data in support of the effectiveness of RSV prophylaxis for a second RSV season, members with more severe CLD requiring medical therapy for pulmonary or cardiac dysfunction may receive benefit from a second season's administration *up to 24 months of age, chronological, at the start of RSV season.*

2. Prematurity

- a. Infants born at under 28 weeks of gestation may benefit from prophylaxis if they are <12 months of age at the start of RSV season
- b. Infants born at 29-31 weeks of gestation may benefit from prophylaxis if they are <6 months of age at the start of RSV season
- c. Infants born at 32-35 weeks of gestation may benefit from prophylaxis if they are
- · School age siblings living in the home
- < 6 months of age at the start of RSV season, provided they have AT LEAST 2 of the following Risk Factors:
- Child-care attendance
- Exposure to environmental pollutants (including tobacco smoking if the family continues to expose the infant to tobacco smoke in the home)
- Severe neuromuscular disease
- Congenital abnormalities of the airways

3. Congenital Heart Disease

Infants and children who are under 24 months of age or younger with hemodynamically significant cyanotic and acyanotic congenital heart disease as further defined by any of the following:

- Receiving medication to control congestive heart failure
- Moderate to severe pulmonary hypertension
- Cyanotic congenital heart disease
- * See below section for additional information where there is insufficient information to support Synagis use in hemodynamically insignificant CHD.

4. Severe immunodeficiency

Infant or child with severe immunodeficiencies (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome) who are < 24 months of age at the start of the RSV season.

5. Early or late administration

Onset and duration of the RSV season may vary from region-to-region and from year-to-year. Decisions regarding the initiation and specific duration of prophylaxis should be individualized according to the duration of the RSV season. For Synagis requests that meet the CIGNA HealthCare medical necessity criteria, the physician's clinical judgment regarding the duration of therapy and the early or late administration of Synagis is sufficient for the approval. This will potentially account for the early administration beginning in October, where early administration is warranted, and continue the coverage through April. According to the CDC and AAP, a total of 5 doses are generally sufficient to provide protection during the entire RSV season which is from November to March for most regions. With two additional months to cover the early and late administration, CIGNA HealthCare will cover up to a total of 7 doses to be authorized where patients meet medical necessity criteria during the RSV season.

6. All-year-around dosing request

CIGNA HealthCare requires that providers supply epidemiologic data on RSV activity from the CDC or their regional health department to support medical necessity for more than seven doses.

Note:

- As long as criteria in 1,2, 3, or 4 and 5 are met from above, Synagis may be authorized for
- administration from October to April for a total of 7 doses.
- As the epidemiology of RSV may vary from area to area, per CDC guidance or regional health

department recommendations, documented activity in the community may allow for earlier or later administration, (e.g. October or April).

CIGNA HealthCare does not cover palivizumab (Synagis®) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

 Infants and children with hemodynamically insignificant heart disease (atrial septal defect, small

ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarction of the aorta

and patent ductus arteriosus)

- Infants with CHD with lesions corrected by surgery (unless require continuing medication for CHF)
- Infants with mild cardiomyopathy who are not receiving medical therapy
- Synagis prophylaxis for RSV in immunocompromised patients
- Use of Synagis in patients with cystic fibrosis
- Treatment of RSV disease

Synarel Prior Auth Criteria:

CIGNA HealthCare covers nafarelin (Synarel®) as medically necessary when ANY of the following indications are met:

- central precocious puberty
- endometriosis

AND

failure, contraindication or intolerance to a trial of oral contraceptives (nafarelin therapy not to exceed six months)

CIGNA HealthCare does not cover the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- uterine fibroids, preoperative use
- dysfunctional uterine bleeding, preoperative use

Tagretin Prior Auth Criteria:

CIGNA Pharmacy Management covers Tagretin when all of the following medical necessity criteria are met:

• For the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who were unresponsive to at least one prior systemic therapy.

Tarceva Prior Auth Criteria:

CIGNA HealthCare covers erlotinib (Tarceva[™]) as medically necessary when ANY of the following indications are met:

- treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND failure of at least one prior chemotherapy regimen
- treatment of locally advanced, unresectable or metastatic pancreatic cancer

CIGNA HealthCare does not cover the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- treatment of ovarian cancer
- treatment of inoperable advanced squamous cell carcinoma of the head and neck
- treatment of glioblastoma multiforme
- treatment of bronchioloalveolar cell carcinoma

Trelstar Prior Auth Criteria:

CIGNA Pharmacy Management covers triptorelin (Trelstar) when one of the following medical necessity criteria is met:

• :Treatment of Prostate Cancer (Advanced)

Tretinoin – Topical Prior Auth Criteria:

CIGNA Pharmacy Management covers Topical Tretinoin Therapy when one of the following medical necessity criteria is met:

- Treatment of Acne Vulgaris
- Treatment of Senile comedones
- Treatment of Lichen planus oral conditions, including Geographic tongue
- Treatment of Icthyosiform, bullous congenital
- Treatment of Icthyosis (lamellar, vulgaris)
- Treatment of Keratosis pilaris; Keratosis follicularis (Darier's disease, Darier-White disease)
- Treatment of Verrucae, Verruca planar
- Treatment of Actinic Keratosis when in combination with topical 5-Fluorouracil
- Treatment of Rosacea / Acne Rosacea

CIGNA Pharmacy Management does not cover Topical Tretinoin Therapy because it is considered not medically necessary or of unproven benefit or cosmetic for the following diagnoses (this list may not be all-inclusive):

- Treatment of Actinic Keratosis as monotherapy
- Treatment of Mollusca Contagiosa
- Treatment of Dermaheliosis Basal Cell carcinoma
- Treatment of Squamous Cell Carcinoma
- Treatment of Lentigines, solar, senile (liver spots)
- Treatment of Dermal elastosis, wrinkling, pigmentary changes
- Treatment of Keratoanthomas
- Treatment of Melanomas (general)
- Treatment of Cervical dysplasia
- Treatment of Callosites
- Treatment of Eczema
- Treatment of Folliculitis (general and steroid induced)
- Treatment of Pseudofolliculitis
- Treatment of Hyperkeratosis (epidermolytic, palmaris et plantaris)
- Treatment of Leukoplakia (general and hairy)
- Treatment of Nevus comedonicus
- Treatment of Papillomatosis
- Treatment of Psoriasis
- Treatment of Androgenic alopecia
- Treatment of Collagenosis
- Treatment of Striae distense (stretch marks)
- Wrinkle reduction
- Skin lightening

Vaccine Prior Auth Criteria, Not Otherwise Specified:

CIGNA Pharmacy Management covers vaccines with criteria not otherwise specified as medically necessary when the following indications are met:

- Recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) or
- Recommended by the American Academy of Pediatrics (AAP)

Velcade Prior Auth Criteria:

CIGNA HealthCare covers bortezomib (Velcade.) as medically necessary when the following indications are met:

• treatment of multiple myeloma in patients who have received at least ONE prior therapy and have demonstrated disease progression on the last therapy

CIGNA HealthCare does not cover for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

• as monotherapy or in combination with other drugs including other chemotherapeutics for the

treatment of ANY of the following indications:

chronic lymphocytic leukemia

pancreatic cancer

colorectal cancer

advanced non-small cell lung cancer (NSCLC)

prostate cancer

breast cancer

ovarian cancer

renal cell cancer

non-Hodgkin's lymphoma (NHL)

advanced bronchioloalveolar carcinoma (BAC) and adenocarcinoma with BAC-like features

newly diagnosed multiple myeloma

Ventavis Prior Auth Criteria:

CIGNA HealthCare covers iloprost inhalation solution (Ventavis®) as medically necessary when BOTH of the following indications are met:

- for treatment of pulmonary arterial hypertension (PAH)
- for patients with New York Heart Association (NYHA) Class III and Class IV

Vesanoid Prior Auth Criteria:

CIGNA Pharmacy Management covers oral tretinoin (Vesanoid \circledR) when the following medical necessity criteria are met:

• For the treatment of acute promyelocytic Leukemia

VFEND Prior Auth Criteria:

CIGNA Pharmacy Management covers oral Voriconazole (VFEND®) when the following medical necessity criteria are met:

- Used in the primary treatment of acute invasive aspergillosis or
- Treatment for fungal infection caused by Scedosporium apiospermum and Fusarium spp. in patients intolerant of, or refractory to, other therapy or
- Diagnosis of Esophageal Candidiasis and failure, contraindication, or intolerance when treated with fluconazole

Viadur Prior Auth Criteria:

CIGNA Pharmacy Management covers leuprolide (Viadur) when the following medical necessity criteria are met:

• Treatment of Prostate Cancer (Advanced)

Vidaza Prior Auth Criteria:

CIGNA Pharmacy Management covers Azacitidine (Vidaza™) as medically necessary when the following indications are met:

- Diagnosis of Myelodysplastic Syndrome, including the following subtypes:
 - o Refractory anemia (RA),
 - o Refractory anemia with ringed sideroblasts (RARS),
 - o Refractory anemia with excess blasts (RAEB-1, RAEB-2),
 - o Refractory anemia with excess blasts in transformation (RAEB-t), and
 - o Chronic myelomonocytic leukemia (CMML)

CIGNA Pharmacy Management does not cover Azacitidine (Vidaza™) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- Acute leukemias,
- Chronic myelogenous leukemias,
- Adenocarcinomas,
- Solid tumors, and other
- Metastatic cancers

Xolair Prior Auth Criteria:

CIGNA Pharmacy Management covers Omalizumab (Xolair®) when the following medical necessity criteria are met:

- Age 12 or greater and
- Diagnosis of Moderate Persistent or Severe Persistent Asthma and
- Asthma is inadequately controlled on current medications and
- Have a positive skin test or in vitro reactivity to a perennial aeroallergen and
- Require regular use of inhaled corticosteroids and another controller therapy such as a Long Acting Beta Agonist or Leukotriene Receptor Antagonist

CIGNA Pharmacy Management does not cover Omalizumab (Xolair[®]) because it is considered not medically necessary or of unproven benefit for the following diagnoses (this list may not be all-inclusive):

- Allergic Rhinitis
- Atopic Dermatitis
- Food Allergy
- Prevention of Anaphylaxis

Zoladex Prior Auth Criteria:

CIGNA HealthCare covers goserelin (Zoladex®) as medically necessary when ANY of the following indications are met:

- prostate cancer (locally confined and advanced)
- advanced breast cancer (goserelin 3.6 mg only)
- dysfunctional uterine bleeding (goserelin therapy not to exceed two months for preoperative use;

goserelin 3.6 mg only)

endometriosis

AND

failure, contraindication or intolerance to a trial of oral contraceptives (goserelin therapy not to exceed six months; goserelin 3.6 mg only)

CIGNA HealthCare does not cover the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):

- uterine fibroids, preoperative use
- · central precocious puberty

Zometa Prior Auth Criteria:

Zoledronic Acid (Zometa®) may be covered as part of the management of members when

medical necessity has been established. Coverage for Zoledronic Acid (Zometa®) may be

provided without further review when the request establishes the following:

- For the treatment of Hypercalcemia of malignancy (HCM).
- For the treatment of multiple myeloma and bone metastases of solid tumors -- to be used in conjunction with standard antineoplastic therapy.

Zyvox Prior Auth Criteria:

CIGNA Pharmacy Management covers Linezolid ($Zyvox^{TM}$) when one of the following medical necessity criteria is met:

- Treatment of infections caused by methicillin-resistant or oxacillin-resistant *S. aureus* (MRSA or ORSA)
- Treatment of infections caused by methicillin-resistant or oxacillin-resistant *S. epidermidis* (MRSE or ORSE)
- Treatment of infections caused by vancomycin-resistant *enterococcus* (VRE)