

Specialty Guideline Management (SGM) Therapy and Drug Overview

SGM is a comprehensive utilization management program that helps promote patient safety and ensure appropriate utilization of specialty medications. With robust criteria and a higher touch clinical review, SGM helps payors control specialty utilization spend and keep patients on their path to better health.

ACROMEGALY

Acromegaly is a hormonal disorder caused by excessive production of growth hormone by the pituitary gland. It is a slowly progressive disease that mainly leads to soft tissue and bone overgrowth, which can result in severe disfigurement, serious complications and premature death.

Bynfezia
Mycapssa
octreotide (Sandostatin)
Sandostatin LAR Depot

Signifor LAR
Somatuline Depot,
Lanreotide Acetate
Somavert

ALCOHOL AND OPIOID DEPENDENCY

Alcohol and opioid dependence can have severe impact on both physical and mental health. Vivitrol is an injectable medication used to treat alcohol and opioid dependence.

Vivitrol

ALOPECIA AREATA

Alopecia areata is a chronic autoimmune disorder characterized by hair loss ranging from small patches of hair loss on the scalp to total loss of scalp hair (alopecia totalis) or loss of the entire scalp and body hair (alopecia universalis). Alopecia areata is the most common cause of inflammation-induced hair loss.

Olumiant

ALPHA1-ANTITRYPSIN (AAT) DEFICIENCY

AAT deficiency is a hereditary disorder that increases the risk of lung disease (e.g., emphysema, chronic obstructive pulmonary disease), liver disease and other conditions. AAT is a serum protein that protects the lungs from enzymes of inflammatory cells, especially neutrophil elastase. AAT replacement products are used to treat AAT deficiency.

Aralast NP
Glassia

Prolastin-C
Zemaira

AMYLOIDOSIS

Amyloidosis is a systemic disorder characterized by the extracellular deposition of amyloid fibrils into body organs. Hereditary transthyretin (TTR)-mediated amyloidosis is caused by mutations that destabilize the TTR protein—a plasma transport protein for thyroxine and vitamin A—resulting in TTR that degrades from its native form and aggregates into amyloid fibrils

that accumulate in various organs and tissues. This accumulation and eventual amyloidosis can present as progressive sensory or motor neuropathy. These medications help slow/reduce progression of the disease.

Amvuttra
Onpattro**
Tegsedi**

Vyndamax
Vyndaqel

ANEMIA

Anemia is caused by a reduction of functional red blood cells (RBCs), increased destruction of RBCs or blood loss. This results in an inadequate supply of oxygen-rich blood to vital organs which can lead to weakness, fatigue, dizziness and shortness of breath. If severe enough, some patients require blood/blood product transfusions. Medications in this category target the underlying cause(s) of anemia, typically by either stimulating the production of circulating RBCs or inhibiting their destruction. Of special note, Zynteglo is a one-time gene therapy for patients with beta-thalassemia who require regular RBC transfusions. Beta-thalassemia is a hereditary form of anemia caused by mutations in the beta-globin gene resulting in reduced production of hemoglobin.

Aranesp
Enjaymo
Epogen
Mircera

Procrit
Reblozyl
Retacrit
Zynteglo*

ASTHMA

Asthma is a chronic inflammatory disorder of the airways characterized by airway inflammation and periods of reversible airway obstruction. Asthma is frequently triggered by environmental allergens such as dust mites and pollens. Common symptoms include wheezing, coughing, chest tightness and shortness of breath. These symptoms may result in emergency room visits and hospitalization. People with allergic asthma often have specific immunoglobulin E (IgE) antibodies to allergens. These medications help to inhibit the cytokine-mediated inflammation that is key to asthma pathogenesis.

Cinqair
Dupixent
Fasenra

Nucala
Tezspire
Xolair

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ATOPIC DERMATITIS

Atopic dermatitis (AD) is a chronic, inflammatory skin condition which can occur at any age (occurs most frequently in children), characterized by a dry, red rash with itching. Clinical features of atopic dermatitis include skin dryness, erythema, oozing and crusting, and lichenification. Pruritus is a hallmark of the condition and is responsible for much of the disease burden for patients and their families.

Adbry
Cibinqo

Dupixent
Rinvoq

BONE DISORDERS—OTHER

Bone disorders can manifest in a variety of ways, most often resulting in impaired development of bones and teeth. Primary causes are genetic mutations that impact important growth factors that can disrupt and/or impede bone formation. These medications replace defective proteins important to bone development.

Strensiq**

Voxzogo

BOTULINUM TOXINS

Botulinum toxin is commonly used for treatment of cervical dystonia, spasticity, strabismus, blepharospasm and urinary incontinence. It is also used for prophylaxis of chronic migraine headaches. These medications work by blocking the affected nerves, which results in weakening or paralysis of the related muscles.

Botox
Dysport

Myobloc
Xeomin

CARDIAC DISORDERS

Tikosyn is an antiarrhythmic agent used for conversion to and maintenance of normal heart rhythm in people with atrial fibrillation or atrial flutter. It works by blocking the cardiac potassium ion channels.

Camzyos

Tikosyn

CENTRAL PRECOCIOUS PUBERTY (CPP)

CPP is a condition that causes early onset of puberty in both boys and girls due to early activation of hormones that are responsible for puberty, the underlying cause of which is currently unknown. These medications suppress the release of hormones that initiate puberty.

Fensolvi
Lupron Depot-PED

Supprelin LA
Triptodur

CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS)

CAPS are comprised of three rare genetic autoinflammatory syndromes: familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS) and neonatal-onset multisystem inflammatory disease/chronic infantile neurologic

cutaneous and articular syndrome (NOMID/CINCA). Common symptoms among the three disorders include periodic fever, inflammation and recurrent urticaria-like skin rash. These interleukin-1 targeted therapies are used to reduce inflammation.

Arcalyst
Ilaris

Kineret

CUSHING'S

Cushing's syndrome is an endocrine disorder caused by overproduction of the hormone cortisol. Excess cortisol can result in weight gain, high blood pressure, depression and diabetes. These medications are indicated for patients who are not candidates for pituitary surgery or for whom surgery was unsuccessful. These medications work by reducing cortisol levels in the body.

Isturisa
Korlym

Recorlev
Signifor

CYSTIC FIBROSIS (CF)

CF is a hereditary disease of secretory glands, including the glands that produce mucus and sweat. CF causes mucus to become thick and sticky, resulting in impaired mucus clearance of the airways and ongoing (chronic) pulmonary infections. Some of these drugs (e.g., Tobramycin inhalation solution, TOBI Podhaler, Bethkis, Kitabis Pak, Cayston) are inhaled antibiotics used to treat the opportunistic bacterial infections commonly found in people with this condition. Pulmozyme and Symdeko help decrease sputum viscosity and improve pulmonary function. Kalydeco, Orkambi and Trikafta are used for CF patients with certain genetic mutations. Bronchitol rehydrates airways to help improve pulmonary function.

Bethkis
Bronchitol
Cayston
Kalydeco
Kitabis Pak
Orkambi

Pulmozyme
Symdeko
TOBI Podhaler
tobramycin inhalation solution (TOBI)
Trikafta

DUPUTRYENS CONTRACTURE

Dupuytren's contracture is a condition that affects one or both hands. It causes the tissue under the skin on the palm to thicken. Over time, this can affect the finger muscles and how the fingers move. Dupuytren's contracture usually gets worse slowly over many years. Most often, it involves the ring finger and little finger. Treatment is based on the severity of symptoms. Treatment can't stop the condition from getting worse, but it can help reduce symptoms. Collagenase injection therapy in the palm of the hand is most effective for patients with less severe contractures or with early-stage disease and can break up and soften thick tissue.

Xiaflex

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ELECTROLYTE DISORDERS

Electrolyte disorder(s) can result in significant morbidity and involve a multitude of potential causes. Signs and symptoms can include nausea, vomiting, confusion, fatigue and seizures, and if left untreated can lead to death. Low sodium levels should be corrected gradually to avoid severe neurologic damage and death. Samsca helps to correct significantly low sodium levels due to conditions such as heart failure and certain hormone imbalances. Keveyis is used to treat primary periodic paralysis secondary to abnormal—either low or high—serum potassium levels by normalizing those levels.

Keveyis (tolvaptan) **Samsca**

ENZYME DEFICIENCY DISORDERS—OTHER

Enzyme deficiency disorders are inherited conditions that result in the shortage or total absence of particular enzymes in the body. Type 1 plasminogen deficiency is a genetic disorder characterized by the lack of the enzyme plasminogen. Low levels of plasminogen result in a buildup of fibrin, a protein responsible for clotting at wound sites and promotion of new tissue growth. This increase in fibrin causes the hallmark symptoms of type 1 plasminogen deficiency, particularly the growth of thick, woody, inflamed growths along mucous membranes, known as ligneous conjunctivitis. Ligneous conjunctivitis is most common around the eyes, mouth, lungs, gastrointestinal tract, and female reproductive tract. Ryplazim is a plasma-derived plasminogen used to replace deficient plasminogen in these patients.

Pyrukynd **Ryplazim**

ENDOCRINE DISORDERS-OTHER

An endocrine disorder occurs when an endocrine-secreting gland (e.g., pancreas, pituitary, thyroid, or adrenal) produces either too much or too little of a specific hormone. Type 1 diabetes (historically known as “juvenile onset diabetes”) is now thought to be a chronic autoimmune disorder caused by one’s own immune system attacking insulin-producing pancreatic beta cells, ultimately leading to lifelong insulin dependence. Stages 1 and 2 of the disease are presymptomatic and insulin injections are not part of standard treatment. In stage 1, the immune system starts attacking beta cells, but blood sugar levels are normal. In stage 2, as loss of functional beta cell progresses, blood sugar levels can at times be too low or too high. As the disease progresses to stage 3, beta cells are damaged in significant numbers to not produce enough insulin, resulting in the typical clinical signs and symptoms of diabetes and the requirement for insulin. Tzielid is a monoclonal antibody used to delay

the onset of full-blown (i.e., stage 3) type 1 diabetes by increasing the amount of regulatory T cells.

Tzielid

GASTROINTESTINAL DISORDERS—OTHER

Short bowel syndrome (SBS) causes poor absorption of nutrients; resulting from Crohn’s disease, cancer and cancer treatment, trauma, other intestinal damage/blockage or when parts of the small intestine are absent due to surgery or a congenital condition. Symptoms of SBS include weight loss, malnutrition, diarrhea and dehydration. These medications address a variety of the symptoms or causes of SBS.

Bylvay** **Livmarli**
Chenodal **Ocaliva**
Cholbam **Zorbitive**
Gattex

GOUT

Gout is a condition caused by high uric acid levels resulting in painful, swollen and tender joints that can lead to bone damage. Krystexxa is used for refractory chronic gout that cannot be controlled by standard gout medications. Krystexxa converts uric acid to a more water-soluble form that is more easily eliminated from the body.

Krystexxa

GROWTH HORMONE (GH) AND RELATED DISORDERS

GH is produced by the pituitary gland and promotes growth and regulates metabolism. GH deficiency can be caused by congenital or acquired conditions. Recombinant GH products are used to replace GH in people with GH deficiency, regardless of the underlying cause.

Genotropin **Omnitrope**
Humatrope **Saizen**
Increlex **Skytrofa**
Norditropin **Sogroya**
Nutropin AQ **Zomacton**

HEMATOPOIETICS

Mozobil is used in combination with granulocyte colony stimulating factor in people with lymphoma and myeloma who are undergoing stem cell collection and transplantation.

Mozobil

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HEMOPHILIA AND RELATED BLEEDING DISORDERS

Many inherited coagulation disorders manifest as excess bleeding. These include von Willebrand disease (vWD) and fibrinogen disorders. Hemophilia conditions are caused by a deficiency of coagulation factor VIII (hemophilia A) or factor IX (hemophilia B). vWD is the most common inherited bleeding disorder and occurs when there is a defect in the quantity or quality of von Willebrand factor. Inherited deficiencies of factors XIII, XI, X, VII, V and II (prothrombin) are referred to as rare (or recessive) inherited coagulation disorders (RICDs). Factor replacement therapy products replace the missing clotting factors to help prevent/treat spontaneous or traumatic bleeds and to recover from surgery. Hemgenix is a one-time gene therapy for patients with Hemophilia B. Hemgenix provides a working copy of Factor IX (F9) gene resulting in increased factor IX production. Elevated levels of factor IX from gene therapy reduce the risk of bleeding and decrease, or potentially eliminate, the need for regular, long-term prophylaxis with factor replacement therapy(s).

Advate
Adynovate
Afstyla
Alphanate
AlphaNine SD
Alprolix
Altuviiiio
BeneFIX
Coagadex
Corifact
Eloctate
Esperoct
Feiba NF
Feiba VH
Fibryga
Hemgenix*
Hemlibra
Hemofil M
Humate-P
Idelvion
Ixinity

Jivi
Koate-DVI
Kogenate FS
Kovaltry
Mononine
Novoeight
NovoSeven
Nuwiq
Obizur
Profilnine SD
Rebinyn
Recombinate
Riastap
Rixubis
Sevenfact
Stimate Nasal Spray
Tretten
Vonvendi
Wilate
Xyntha

HEPATITIS C

Hepatitis C is an infectious disease that causes inflammation of the liver. If left untreated, chronic infection may lead to liver damage or cirrhosis, liver cancer, or liver failure requiring a liver transplant. The treatment regimens and their durations vary based on

hepatitis C virus (HCV) genotype, previous treatment history and other factors. The goal of HCV treatment is to prevent the complications of chronic infection by eradicating the virus.

Epclusa
Harvoni
Mavyret
Pegasys
ribavirin

Sovaldi
Viekira Pak
Vosevi
Zepatier

HEREDITARY ANGIOEDEMA (HAE)

HAE is a rare, but potentially life-threatening disorder of the immune system. HAE is characterized by recurrent episodes of severe swelling in the skin and soft tissues. These episodes can occur in the throat, tongue, face, extremities or abdomen. Management of HAE includes short-term and long-term prophylaxis as well as treatment of acute attacks.

Berinert**
Cinryze**
Firazyr**
Haegarda**

Kalbitor**
Orladeyo**
Ruconest**
Takhzyro**

HORMONAL THERAPIES

Hormonal therapies are used to treat cancer and other medical conditions. Lupron is also used for infertility and central precocious puberty (CPP).

Aveed
Camcevi
Eligard
Fensolvi
Firmagon
leuprolide acetate
Leuprolide Acetate
Leuprolide Acetate Depot

Lupaneta Pack
Lupron Depot
Lupron Depot-PED
Natpara
Supprelin LA
Trelstar
Triptodur
Zoladex

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

HIV is the virus that causes acquired immune deficiency syndrome (AIDS). HIV attacks the immune system by destroying CD4 positive (CD4+) T cells, a type of white blood cell that is vital to fighting off infection. Fuzeon, an antiviral medication, is indicated for the treatment of HIV-1 infection in treatment experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Cabenuva is a long-acting injectable antiviral medication indicated for the treatment of virologically suppressed HIV-1 patients who have no history of treatment failure and no resistance to the drug components.

Cabenuva
Egrifta

Fuzeon
Serostim

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IMMUNE DEFICIENCIES AND RELATED DISORDERS

Immune deficiencies represent a group of disorders in which the immune system's response is weakened or absent. These medications help treat conditions such as primary immunodeficiency, chronic inflammatory demyelinating polyneuropathy, and activated phosphoinositide 3-kinase delta syndrome (APDS).

Asceniv	Gamunex
Bivigam	Hizentra
Cutaquig	HyQvia
Cuvitru	Joenja**
Flebogamma	Octagam
GamaSTAN S/D	Panzyga
Gammagard	Privigen
Gammaked	Xembify
Gammaplex	

INFECTIOUS DISEASE

Unusual (i.e., atypical) infectious diseases require novel anti-infective agents, especially for use in susceptible populations. Actimmune is used to treat chronic granulomatous disease (CGD), an inherited immunodeficiency disorder that makes a person vulnerable to various opportunistic infections, by reducing the frequency and/or severity of serious infections associated with CGD. Arikayce inhalation suspension is used for the treatment of mycobacterium avium complex (MAC) lung disease in adults who have limited or no alternative treatment options. Rebyota is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in the intestinal tract, after antibiotic treatment for recurrent CDI.

Actimmune	Veklury
Arikayce	Vowst
Rebyota	

INFERTILITY

Infertility is medically defined as an inability to achieve pregnancy after 12 months or more of trying to conceive. Infertility medications can be used in assisted reproductive technology procedures, such as in vitro fertilization, or in ovulation induction procedures to help achieve pregnancy.

Cetrotide	ganirelix acetate,
chorionic	Fyremadel
gonadotropin	Gonal-F
(Novarel, Ovidrel, Pregnyl)	leuprolide
Follistim AQ	Menopur

INFLAMMATORY BOWEL DISEASE (IBD)

IBD covers a number of disorders where the digestive tract becomes inflamed due to abnormal actions by the immune system. The inflammation can result in pain, diarrhea and unintended weight loss. These medications help to reduce the inflammation to relieve symptoms and prevent progressive damage to the digestive tract.

Amjevita	Renflexis
Avsola	Rinvoq
Cimzia	Simponi
Entyvio	Skyrizi
Humira	Stelara[†]
Inflectra	Tysabri
infliximab (Remicade)	

IRON OVERLOAD

Iron is an important component of hemoglobin, the chemical in red blood cells that transports oxygen. Some people accumulate excessive amounts of iron due to genetic disorders or through repeat blood transfusions. The excess iron is deposited in the liver and other organs where it can interfere with the organ's function. These medications assist in the removal of iron from the body.

deferiprone (Ferriprox)	deferasirox (Jadenu)
deferoxamine (Desferal)	Exjade

LIPID DISORDERS

Lipid disorder(s), whether inherited or acquired, cause high cholesterol levels and early onset of cardiovascular disease. Homozygous familial hypercholesterolemia (HoFH) is a rare, but severe, form of hypercholesterolemia that is associated with very high levels of cholesterol, leading to cholesterol deposits in the tendons, skin or other areas, severe heart disease at a young age, and a poor response to standard lipid-lowering therapy. These medications help to substantially lower cholesterol levels and related cardiovascular complication risk in affected patients.

Evkeeza	Praluent
Juxtapid	Repatha
Leqvio	

LIPODYSTROPHY

Lipodystrophy is a rare disorder caused by abnormalities in fat tissue distribution and a loss of the fat tissue necessary for normal metabolism. Lipodystrophy may lead to complications such as diabetes and lipid disorders. Myalept is used with dietary changes to treat lipodystrophy.

Myalept

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LYSOSOMAL STORAGE DISORDERS (LSD) AND RELATED DISORDERS

Lysosomes contain enzymes within cells that digest large biomolecules into smaller usable fragments. LSDs are genetic disorders caused by the lack of an enzyme that breaks down these large molecules. Over time, the build-up of the undigested substance damages the cells and thus the functioning of the organ to which they belong. These medications treat LSDs by replacing the missing enzyme.

Adagen	Kanuma
Aldurazyme	Lamzede
Brineura*	Lumizyme
Cerdelga	Mepsevii
Cerezyme	Naglazyme
Cystagon	Nexviazyme
Cystaran	Nityr
Cystadane	Orfadin
Cystadrops	Procysbi
Elaprase	Vimizim
Elelyso	Vpriv
Fabrazyme	Xenpozyme
Galafold	Zavesca

MENTAL HEALTH CONDITIONS

Mental health conditions affect a person's emotional, psychological and social well-being. Mental health conditions — including depression, anxiety, bipolar disorder and schizophrenia — are common in the United States. Spravato is indicated for patients with treatment-resistant depression. Zulresso is indicated for the treatment of postpartum depression.

Spravato	Zulresso
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MOVEMENT DISORDERS

Medical conditions or disorders that impact control of limb use can be severely limiting to individual's quality and longevity of life. These medications help treat various movement disorders such as involuntary spasms or jerky movements associated with Huntington's Chorea, Parkinson's disease, involuntary movements (Tardive Dyskinesia) associated with the use of anti-psychotic medications, amyotrophic lateral sclerosis, and Friedreich's ataxia.

Apokyn	Nuplazid
Austedo	Qalsody*
Austedo XR	Radicava
droxidopa (Nothera)	Radicava Ors
Duopa	Relyvrio
Inbrija	Skyclarys
Ingrezza	tetrabenazine (Xenazine)
Kynmobi	

MULTIPLE SCLEROSIS (MS)

MS is characterized by damage to nerves in the brain and spinal cord that prevents those nerves from communicating. When the nerves cannot communicate, people begin to lose control of muscle movements and other functions. Ampyra helps improve walking ability in people with MS. The other medications help prevent progression of the disease to limit the loss of function.

Aubagio	Kesimpta
Avonex	Lemtrada
Bafiertam	Mavenclad
Betaseron	Mayzent
Briumvi	Ocrevus
dalfampridine (Ampyra)	Plegridy
dimethyl fumarate	Ponvory
(Tecfidera)	Rebif
Copaxone	Tascenso ODT
Extavia	Tysabri
fingolimod (Gilenya)	Vumerity
Glatopa	Zeposia

MUSCULAR DYSTROPHY

Duchenne Muscular Dystrophy (DMD) is a rare, inherited muscle disease that causes profound progressive weakness in children. The clinical onset of weakness usually occurs between 2-3 years of age.

Amondys 45**	Viltepso**
Emflaza	Vyondys 53**
Exondys 51**	

NEUROLOGICAL DISORDERS

Neurological disorders can manifest in a variety of ways, but typically involve degeneration or dysfunction of some component of the central nervous system (brain, spinal cord and associated neurons). Medications listed below help treat neurological disorders such as Alzheimer's disease, cerebral adrenoleukodystrophy (CALD), and Rett syndrome.

Aduhelm*	Leqembi*
Daybue	Skysona*

NEUROMUSCULAR

This category includes a wide-range of diseases affecting the peripheral nervous system, which consists of all the motor and sensory nerves that connect the brain and spinal cord to the rest of the body. Evrysdi, Spinraza and Zolgensma are used for the treatment of Spinal Muscular Atrophy (SMA). SMA is a group of hereditary diseases that progressively destroy nerve cells in the brain stem and spinal cord that control essential skeletal muscle activity such as speaking, walking, breathing and swallowing. This progressive muscle wasting disease leads to complications such as paralysis and permanent home

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ventilation over time. Vyvgart is used to treat generalized Myasthenia Gravis (gMG). Patients with gMG produce antibodies that can attack muscles and cause general fatigue and profound muscle weakness.

Evrysdi**

Soliris**

Spinraza*

Ultomiris**

Vyvgart**

Zolgensma*

NEUTROPENIA

Neutropenia is an abnormally low count of neutrophils, a type of white blood cell that protects the body from infection. The reduced number of neutrophils may be due to a number of causes, but it is a common adverse effect of cancer chemotherapy. These medications stimulate the production of more white blood cells.

Fulphila

Fynetra

Granix

Leukine

Neulasta

Neupogen

Nivestym

Nyvepria

Releuko

Rolvedon

Stimufend

Udenyca

Zarxio

Ziextenzo

OCULAR DISORDERS

Any condition that adversely affects a component of the eye, regardless of the etiology, is considered an ocular disorder. Medications listed below help treat ocular disorders such as age-related macular degeneration, diabetic macular edema, geographic atrophy, neurotrophic keratitis, thyroid eye disease, and macular edema associated with uveitis.

Alymsys

Avastin

Beovu

Byooviz

Cimerli

Eylea

Jetrea

Lucentis

Macugen

Mvasi

Oxervate

Susvimo

Syfovre

Tepezza

Vabysmo

Vegzelma

Visudyne

Xipere

Zirabev

ONCOLOGY

These medications are used to treat various cancers. Each agent targets different tumor types.

Abecma*

**abiraterone acetate
(Zytiga)**

Adcetris

Alecensa

Aliqopa

Alunbrig

Alymsys

Arzerra

Asparlas

Avastin

Ayvakit

azacitidine (Vidaza)

Balversa

Bavencio

Beleodaq

Belrapzo

Bendamustine

Bendeka

Besponsa

Besremi

bexarotene (Targretin)

Blenrep

Blinicyto

Bosulif

Braftovi

Breyanzi*

Brukinsa

Cabometyx

Calquence

capecitabine (Xeloda)

Caprelsa

Carvykti**

Cometriq

Copiktra

Cosela

Cotellic

Cyramza

Danyelza

Darzalex

Darzalex Faspro

Daurismo

decitabine (Dacogen)

Elahere

Elzonris*

Empliciti

Enhertu

Erbitux

Erivedge

Erleada

erlotinib (Tarceva)

Erwinaze

**everolimus (Afinitor,
Afinitor Disperz)**

Exkivity

Farydak

Faslodex

Folotyn

Fotivda

Fusilev

Fyarro

Gavreto

Gazyva

Gilotrif

Halaven

Herceptin

Herceptin Hylecta

Herzuma

Hycamtin Capsules

Ibrance

Iclusig

Idhifa

imatinib (Gleevec)

Imbruvica

Imfinzi

Imjudo

Imlygic

Inlyta

Inqovi

Inrebic

Intron-A

Iressa

Ixempra

Jakafi

Jaypirca

Jelmyto*

Jemperli

Jevtana

Kadcyla

Kanjinti

Keytruda

Khapzory

Kimmtrak

Kisquali/Kisquali Femara

Pak

Koselugo

Krazati

Kymriah*

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Kyprolis
(lapatinib) Tykerb
Lenvima
Libtayo
Lonsurf
Lorbrena
Lumakras
Lumoxiti
Lunsumio
Lutathera*
Lynparza
Lytgobi
Margenza
Mekinist
Mektovi
Monjuvi
Mvasi
Mylotarg
Nerlynx
Nexavar
Ninlaro
Nubeqa
Odomzo
Ogivri
Omisirge*
Oncaspar
Ontruzant
Onureg
Opdivo
Opdualag
Orgovyx
Orserdu
Padcev
Pedmark
Pemazyre
Pepaxto
Phesgo
Piqray
Pluvicto**
Polivy
Pomalyst
Portrazza
Poteligeo
Proleukin
Purixan
Qinlock
Retevmo
Revlimid
Rezlidhia
Rezurock
Riabni
Rituxan

Rituxan Hycela
romidepsin, Romidepsin
(Istodax)
Rozlytrek
Rubraca
Ruxience
Rybrevant
Rydapt
Rylaze
Sarclisa
Scemblix
Sprycel
Stivarga
Strontium Chloride SR-89
Sutent
Sylvant
Synribo
Tabrecta
Tafinlar
Tagrisso
Talzenna
Tasigna
Tazverik
Tecartus*
Tecentriq
Tecvayli
temozolomide
(Temodar)
temsirolimus (Torisel)
Tepmetko
Thalomid
Tibsovo
Tivdak
Trazimera
Treanda
Truseltiq
Tukysa
Turalio
Truxima
Ukoniq
Valchlor
Vectibix
Velcade
Vegzelma
Venclexta
Verzenio
Vitrakvi
Vivimusta
Vizimpro
Vonjo
Votrient
Welireg

Xalkori
Xermelo
Xgeva
Xofigo
Xospata
Xpovio
Xtandi
Yervoy
Yescarta*
Yonsa
Zaltrap
Zejula

Zelboraf
Zepzelca
Zevalin
Zirabev
zoledronic acid
(Zometa)
Zolinza
Zydelig
Zykadia
Zynlonta
Zynyz

OSTEOARTHRITIS (OA)

OA is a common form of arthritis that causes pain, swelling and reduced motion in the affected joints. In people with knee osteoarthritis, the joint fluid breaks down and does not provide adequate cushioning to the joint. These medications supplement the joint fluid to help reduce pain and improve joint function.

Durolane
Euflexxa
Gel-One
Gelsyn-3
Genvisc-850
Hyalgan
Hymovis
Monovisc

Orthovisc
Sodium Hyualuronate
Supartz
Synvisc/Synvisc One
Synojoint
Triluron
Trivisc
Visco-3

OSTEOPOROSIS

Osteoporosis is characterized by reduced bone density and an increased risk of fracture. Bone fractures cause significant pain and may require hospitalization or surgery. These medications increase or stabilize bone density to reduce fracture risk.

Evenity
Prolia
teriparatide (Forteo)

Tymlos
zoledronic acid (Reclast)

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

PNH is a rare disorder where the immune system attacks blood cells. The destruction of red blood cells can cause anemia and blood clots. These medications block the immune system from attacking red blood cells, which helps prevent anemia and blood clots.

Empaveli**
Soliris

Ultomiris

SGM Therapy and Drug Overview *continued*

PHENYLKETONURIA (PKU)

PKU is a rare genetic disorder that impairs the body's ability to metabolize phenylalanine (Phe), an amino acid in the body. If Phe accumulates in the body, it can interfere with brain function, causing impaired thinking and behavioral problems. These medications help the body metabolize Phe to help reduce and prevent the negative effects of Phe accumulation.

Javygtor (sapropterin) **Kuvan**
Palynziq

PRE-TERM BIRTH

Makena is used to reduce the risk of pre-term birth in women who have a history of delivering a baby too early.

Makena

PSORIASIS

Psoriasis is a chronic, inflammatory disease that predominantly affects skin and joints. Plaque psoriasis causes itchy or sore patches of thick, red skin with silvery scales known as plaques. Severe cases can be painful, disfiguring and disabling. These medications help prevent the immune system from attacking the skin. Generalized pustular psoriasis (GPP) is a rare but severe form of psoriasis. It is characterized by recurrent episodes of widespread pustular formations on painful inflamed skin, at times accompanied by fever and systemic inflammation. Severe cases can result in hospitalization and life-threatening complications, such as infection/sepsis.

Amjevita **Rasuvo**
Avsola **RediTrex**
Cimzia **Renflexis**
Cosentyx **Siliq**
Enbrel **Skyrizi**
Humira **Sotyktu**
Ilumya **Spevigo**
Inflectra **Stelara[†]**
infliximab (Remicade) **Taltz**
Otezla **Tremfya**
Otrexup

PULMONARY ARTERIAL HYPERTENSION (PAH)

PAH is a condition characterized by high blood pressure in the lungs, which puts strain on the heart. Symptoms can include shortness of breath, dizziness and decreased exercise tolerance. People with severe disease have difficulty breathing, even at rest. PAH medications help improve symptoms.

Adempas **epoprostenol (Flolan)**
ambrisentan (Letairis) **Opsumit**
bosentan (Tracleer) **Orenitram**

Remodulin sildenafil
(Revatio)
tadalafil (Alyq, Adcirca)
Tadliq
Tyvaso

Tyvaso DPI
Uptravi
Veletri
Ventavis

PULMONARY DISORDERS—OTHER

Idiopathic pulmonary fibrosis is chronic, progressive and ultimately fatal scarring of the lung tissue due to an unknown cause. As the lung tissue becomes more scarred, oxygen cannot move into the body as efficiently and the lungs become less flexible. These medications help stabilize the patient's lung function and slow the rate of lung function decline.

Esbriet **Ofev**

RARE DISORDERS—OTHER

A disease that affects fewer than 200,000 people in the United States is considered a rare disease. Drugs included in the 'Rare Disorder—Other' category include products that treat conditions that meet the definition of a rare disease, have only one or two drugs available for the treatment of that disease, and treat a disease that cannot be classified under any other category in the SGM Therapy Drug List.

Crysvita
Dojolvi
Enspryng
Firdapse
Gamifant*
Givlaari
Luxturna* (gene therapy
for vision loss)

Nulibry
Scenesse*
Tavneos
Uplizna
Vijoice
Zokinvy

RARE GENETIC ADIPOSE TISSUE DISORDER

Rare Genetic Adipose Tissue Disorder is characterized as early onset severe obesity and more likely to be genetic in origin. People living with this early onset type of adipose tissue disorder struggle with extreme, insatiable hunger beginning at a young age, resulting in early onset, severe adiposity and increased body mass index. Variants in POMC, PCSK1 or LEPR genes that impair the melanocortin-4 (MC4) receptor pathway are ultra-rare and are a cause of this disorder.

Imcivree

RENAL DISORDERS

The renal system, which includes the kidneys, is primarily responsible for management of water and solute (e.g., various salts) balance by filtering wastes and extra water from the blood. These medications help to control and

SGM Therapy and Drug Overview *continued*

stabilize hormone, water, calcium, sodium and other solute concentrations.

Filspari
Jynarque
Oxlumo
Parsabiv

Sensipar
Tarpeyo
Thiola/Thiola EC

RESPIRATORY SYNCYTIAL VIRUS (RSV)

RSV is a virus that causes severe cold-like symptoms, which may lead to emergency department visits and hospitalizations. Infants born prematurely and those born with lung and heart disease are at high risk for RSV infection. Synagis is used to prevent RSV infection in high-risk infants.

Synagis

RHEUMATOID ARTHRITIS (RA)

RA is an autoimmune disease that causes pain, swelling and stiffness in joints. If untreated, this swelling may lead to joint deformity and disability. These medications are disease-modifying agents that act on the immune system to slow the progression of RA.

Actemra
Amjevita
Avsola
Cimzia
Enbrel
Humira
Inflectra
infliximab (Remicade)
Kevzara
Kineret
Olumiant

Orencia
Otrexup
Rasuvo
RediTrex
Renflexis
Riabni
Rinvoq
Rituxan
Simponi
Simponi Aria
Xeljanz/Xeljanz XR

SEIZURE DISORDERS

Seizure disorders are disruptive to a person's life and, if uncontrolled, can cause severe problems such as injury to the body or brain, decreased quality of life and intellectual decline in children. These medications help prevent seizures in people with specific types of seizure disorders.

Acthar
Cortrophin
Diacomit
Epidolex

Fintepla
vigabatrin, Vigadrone
(Sabril)
Ztalmy

SICKLE CELL DISEASE

Sickle cell disease is an inherited blood disorder characterized by abnormal hemoglobin (the oxygen-carrying protein within the red blood cells). The abnormal hemoglobin causes distorted (crescent shaped or

"sickled") red blood cells. These abnormally shaped cells restrict the flow of blood and limit oxygen delivery which can lead to severe pain and organ damage.

Adakveo
Endari

Oxbryta

SLEEP DISORDERS

Non-24-hour sleep-wake disorder (N24SWD) is a chronic "circadian rhythm disorder" that occurs when sleep and wake cycles are not synchronized with the normal 24-hour cycle. This condition is most commonly found in people who are totally blind with no perception of light. People with N24SWD cannot synchronize their internal clock with the external 24-hour environment, thus they have difficulty sleeping at night and staying awake during the day. Hetlioz helps treat people with N24SWD. Wakix and Xywav help treat excessive daytime sleepiness in patients with narcolepsy, a separate sleep disorder characterized by an extreme tendency to fall asleep whenever in relaxing surroundings.

Hetlioz
Wakix

Xyrem
Xywav

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

SLE is a systemic autoimmune disease in which antibodies are produced against a person's own tissues. Multiple organs and systems can be involved, including skin, joints, kidneys and other organs. The antibodies and resulting immune response can cause swelling, pain and serious organ/tissue damage. These medications help reduce disease activity in SLE.

Benlysta
Lupkynis

Saphnelo

THROMBOCYTOPENIA

Thrombocytopenia is a condition in which the number of platelets in the bloodstream is below normal levels. Severe thrombocytopenia can result in bleeding episodes secondary to the body's inability to properly clot. Acquired thrombotic thrombocytopenic purpura (aTTP) is an immune-mediated disorder. Cablivi treats aTTP by reducing platelet adhesion and consumption. Immune thrombocytopenia (ITP) is an autoimmune disorder in which there are too few platelets due to an increased destruction and an inappropriately low production rate of new platelets. ITP increases the risk of serious and potentially life-threatening bleeding episodes. Tavalisse reduces platelet destruction to help reduce this risk of bleeding episodes, while Nplate and Promacta are used to increase platelet production and help reduce the risk for serious bleeding

SGM Therapy and Drug Overview *continued*

episodes in patients with ITP. Promacta is also used to treat thrombocytopenia associated with hepatitis C and severe aplastic anemia. Doptelet is indicated for adult patients with chronic ITP who have had an insufficient response to a previous treatment and works by stimulating the bone marrow to increase platelet production. Doptelet and Mulpleta are also used to treat thrombocytopenia prior to a procedure in adult patients with liver disease.

Cablivi

Nplate

Doptelet

Promacta

Mulpleta

Tavalisse

UREA CYCLE DISORDERS (UCDS)

UCDs are genetic disorders caused by a deficiency of one of the enzymes that remove ammonia from the bloodstream. When an enzyme in this process is deficient, ammonia or other urea precursors can accumulate. Accumulation of the ammonia can lead to seizures, respiratory distress and possibly death. These medications help reduce the ammonia level in the blood.

carglumic acid (Carbaglu)

Ravicti

Olpruva

sodium phenylbutyrate

Pheburane

(Buphenyl)

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*Coverage generally provided under a medical benefit due to the manner of administration or other unique characteristics.

**SGM review performed by Medical Director.

†Patient-specific dosing limits.

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