Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Washington Pharmacy Advisory Committee Meeting

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Agenda Topics

- Overview of Disease State
- Indications
- Dosage & Formulations
- Guideline Updates

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Botulinum Toxins

Dermatologics:
Agents For Wrinkles/Lipoatrophy/Other Aesthetic Uses

Neuromuscular Agents: Neuromuscular Blocking Agents- Neurotoxins

Overview of Disease State – Botulinum Toxins

- Cervical dystonia, also known as spasmodic torticollis
  - Painful, localized neurologic movement disorder
  - Symptoms are caused by intermittent or sustained contractions of the neck muscles that control the position of the head. Head position is altered, and the effect can spread down to the shoulders. Head or arm tremor can also be experienced
  - Botulinum toxins are a common treatment for this disorder. The ability to administer botulinum toxins directly to the affected area(s) makes these products a logical first option

- Additional conditions resulting from increased neuromuscular activity for which botulinum toxins are treatment options include
  - Muscle spasticity
  - Eyelid twitching (blepharospasm)
  - Improper eye alignment (strabismus)
  - Axillary hyperhidrosis (excessive armpit sweating due to overactive sweat glands)

Botulinum Toxins – Indications

Drugs	Generic	Indications
abobotulinumtoxinA (Dysport)		▪ Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients ▪ Treatment of upper limb spasticity in adults to decrease the severity of increased muscle tone in elbow, wrist, and finger flexors ▪ Treatment of lower limb spasticity in adults and pediatric patients ≥ 2 years old ▪ Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age
incobotulinumtoxinA (Xeomin)		▪ Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients ▪ Treatment of upper limb spasticity in adults in elbow, wrist, finger, and thumb flexors ▪ Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox) ▪ Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and/or corrugator muscle activity in adults ▪ Treatment of chronic sialorrhea (excessive drooling) in adults
onabotulinumtoxinA (Botox)		▪ Treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain in patients 16 years and older ▪ Treatment of upper limb spasticity in adults to decrease the severity of increased muscle tone in elbow, wrist, finger, and thumb flexors ▪ Treatment of lower limb spasticity in adults to decrease the severity of increased muscle tone in ankle and toe flexors ▪ Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adults ▪ Treatment of blepharospasm associated with dystonia in patients ≥ 12 years ▪ Treatment of strabismus in patients ≥ 12 years ▪ Prophylaxis of headaches in adults with chronic migraine (defined as 15 or more days/month with headache duration of at least 4 hours) ▪ Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication ▪ Treatment of overactive bladder (OAB), with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
rimabotulinumtoxinB (Myobloc)		▪ Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain

Botulinum Toxins – Dosing and Availability

Drugs	Dose	Dosage Forms
abobotulinumtoxinA (Dysport)	**Cervical dystonia:** 500 units IM as a divided dose among affected muscles; Doses ranging from 250 to 1,000 units may be re-administered upon return of clinical symptoms **Spasticity in Adults:** number of units dependent on size, number and location of muscles affected, severity of spasticity, presence of local muscle weakness, response to prior treatment and/or adverse events; (total dose/treatment session, upper and lower limb combined is 1,500 units; no more than 1 mL should generally be administered at any single injection site) •Upper Limb spasticity: dosing ranges between 500 and 1,000 units •Lower Limb spasticity: dosing up to 1,500 units **Lower limb spasticity (pediatric patients ≥ 2 years old):** number of units dependent on size, number, and location of muscles involved, severity of spasticity, presence of local muscle weakness, response to prior treatment, and/or adverse events (total dose/treatment session: 10 to 15 units/kg for unilateral lower limb injections, 20 to 30 units/kg for bilateral lower limb injections, or 1,000 units, whichever is lower; no more than 0.5 mL should be administered to any single injection site)	300 unit vials 500 unit vials
incobotulinumtoxinA (Xeomin)	**Do not exceed 400 units in a treatment session for any indication** **Cervical dystonia:** initial total dose of 120 units IM per treatment session; frequency of repeat treatment depends on clinical response, but should typically be no more frequent than every 12 weeks **Blepharospasm:** 1.25 to 2.5 units per injection site; if known, dose depends on previous dose of onabotulinumtoxinA (Botox); Initial total dose should not exceed 70 units for both eyes (35 units per eye) **Upper limb spasticity:** dosage, frequency, and number of injections sites is dependent on patient size, number and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, response to previous treatment and adverse events **Chronic sialorrhea**: 100 units per treatment session, consisting of 30 units per parotid gland and 20 units per submandibular gland; repeat no sooner than every 16 weeks.	50 unit, 100 unit, 200 unit vials

Botulinum Toxins – Dosing and Availability

Drugs	Dose	Dosage Forms
onabotulinumtoxinA (Botox)	**Cervical dystonia:** Number of units given IM dependent on head and neck position, divided among affected muscles (maximum 50 units/site) **Upper limb spasticity:** number of units dependent on affected muscle **Lower limb spasticity**: 300-400 units (total dose) across ankle and toe muscles **Axillary hyperhidrosis:** 50 units intradermally per axilla **Blepharospasm:** 1.25 to 2.5 units into each of 3 sites per affected eye **Strabismus:** 1.25 to 2.5 units in any 1 muscle **Neurogenic detrusor overactivity:** 200 units IM (divided into 1 mL injections over 30 sites) per treatment into the detrusor muscle **Overactive Bladder (OAB):** 100 units (divided into 0.5 mL injections over 20 sites, approximately 1 cm apart) into the detrusor muscle (avoiding the trigone) **Chronic migraine prophylaxis:** 155 units IM (divided) across 7 head and neck muscle sites In treating one or more indications, the maximum cumulative dose in adults should not to exceed 400 units in a 3-month interval	100 unit, 200 unit vials
rimabotulinumtoxinB (Myobloc)	**Cervical dystonia:** 2,500 to 5,000 units IM divided among affected muscles (for patients with a prior history of tolerating botulinum toxin injections) Patients without prior history should receive a lower initial dose	2,500 unit, 5,000 unit, 10,000 unit vials

Botulinum Toxins – Guidelines

- American Academy of Neurology (AAN), 2016
  - Updated guidelines on the use of botulinum toxins to treat cervical dystonia, blepharospasm, adult spasticity, and headache
  - Overall, the updated guideline states that botulinum toxin is generally safe and effective for these 4 conditions
    - Blepharospasm: Botox and Xeomin are probably effective and should be considered. Dysport is possibly effective and may be considered for treatment
    - Cervical dystonia: Both abobotulinumtoxinA and rimabotulinumtoxinB (Myobloc) are established therapies and should be offered. While data are less robust, Botox and Xeomin are probably effective and should be considered for treatment of cervical dystonia as well
    - Adult spasticity: Dysport, Xeomin, and Botox have demonstrated efficacy and should be offered; Myobloc should also be considered for upper limb spasticity but has less efficacy data in adult spasticity compared to the other agents within the class
    - Headache: Botox has demonstrated efficacy in increasing headache-free days and some improvement in quality of life in patients with chronic migraine; thus, AAN recommends Botox be offered in patients with chronic migraine. However, AAN further notes that Botox has been established as ineffective in episodic migraine and probably ineffective in chronic tension-type headache.

Botulinum Toxins – Guidelines

- American Academy of Neurology (AAN), 2008
  - Earlier guidelines published on the use of botulinum neurotoxin for the treatment of spasticity, movement disorders, and autonomic disorders and pain are considered current for other conditions not specifically updated in the 2016 AAN guidelines
  - Spasticity: recommends that botulinum neurotoxin be offered as a treatment option in children
  - Movement disorders: state that botulinum neurotoxin may be offered for focal arm extremity, dystonia, adductor laryngeal dystonia, and upper extremity essential tremor. Due to limited data, botulinum neurotoxin may also be considered for hemifacial spasm, focal lower limb dystonia, and motor tics
  - Autonomic disorders and pain: recommends that botulinum neurotoxin should be offered for axillary hyperhidrosis and detrusor overactivity and should be considered for palmar hyperhidrosis, drooling, and detrusor sphincter dyssynergia following spinal cord injury. In addition, it may be considered for gustatory sweating and low back pain, but is probably ineffective in episodic migraine and chronic tension-type headache
- Notably, only Botox and Myobloc were available at the time of publication of the 2008 guidelines
- Updates for guidelines related to spasticity (including pediatrics), movement disorders, and autonomic disorders and pain are in progress

Botulinum Toxins

- Dermatologics : Agents For Wrinkles / Lipoatrophy/ Other Aesthetic Uses (**Not be an Apple Health PDL class and is considered cosmetic)**
  - Botox Cosmetic (onabotulinumtoxinA)
- Neuromuscular Agents : Neuromuscular Blocking Agents – Neurotoxins
  - Botox (onabotulinumtoxinA)
  - Dysport (abobotulinumtoxinA)
  - Myobloc (rimabotulinumtoxinB)
  - Xeromin (incobotulinumtoxinA)

Neuromuscular Blocking Agents – Neurotoxins

- **Current Limitations:**
  - Therapeutic class will not be included in the Apple Health PDL at this time
  - Varies based on plan
- **Recommendation:**
  - Continue current limitation

Neuromuscular Blocking Agents – Neurotoxins

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the Neuromuscular Blocking Agents – Neurotoxins drug class listed on slide 11 as recommended."

Motion: Schwilke

2nd: Sanderson

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Hemophilia

Hematological Agents- Misc: Antihemophilic Products

Overview of Disease State – Hemophilia

- Hemophilia is a rare, inherited bleeding disorder where the blood does not clot properly due to an absence of 1 of the coagulation factors present in normal blood
- Hemophilia is identified as an X-linked congenital bleeding disorder that has an estimated frequency of 1 in 5,000 to 10,000 births
  - Typically affects males on the maternal side due to X-linked inheritance; however, females may also rarely be affected but are more commonly carriers of the disease
  - Up to 30% of newly diagnosed cases occur with no prior family history and are attributed to spontaneous mutations in either the F8 or F9 gene
- The World Federation of Hemophilia estimates the global prevalence of hemophilia at around 400,000 persons
  - It is estimated there are approximately 17,000 to 20,000 persons in the United States are afflicted with hemophilia
- There are 2 main types of hemophilia
  - Type A
    - Also known as Factor VIII deficiency, classical hemophilia, or standard hemophilia
    - Far more common than hemophilia B with hemophilia A presenting in 80 to 85% of all hemophilia patients
    - Patients with type A hemophilia exhibit low or missing levels of clotting Factor VIII (8)
  - Type B
    - Also known as Factor IX deficiency or Christmas disease
    - Those with type B have low or missing levels of clotting factor IX (9)

Overview of Disease State – Hemophilia

- Hemophilia can also encompasses a number of other rare factor deficiencies
  - These disorders include deficiencies involving the following factors:
    - Factor I (1) – fibrinogen deficiency
    - Factor II (2) – prothrombin deficiency
    - Factor V (5) – proconvertin deficiency
    - Factor X (10) – Stuart-Prower deficiency
    - Factor XI (11) – hemophilia C or plasma thromboplastin deficiency
    - Factor XII (12) – Hageman factor deficiency
    - Factor XIII (13) fibrin stabilizing deficiency
  - These disorders are far less common than hemophilia A and B, exemplified by factor XIII deficiency which is estimated to occur in 1 in 5 million persons

Overview of Disease State – Hemophilia

- Von Willebrand disease (vWD)
  - Similar to hemophilia A, this is a group of inherited bleeding disorders related to the absence or defects of von Willebrand Factor, a clotting protein, needed to achieve hemostasis
    - Von Willebrand factor binds to Factor VIII and platelets to generate a platelet plug during the clotting process
    - The disease leads to bleeding from impaired platelet adhesion and aggregation, which may be accompanied by reduced levels of Factor VIII
  - The prevalence of the disease is estimated to affect between 1 in 100 to 10,000 individuals; equal in males and females
  - There are 3 major subtypes of vWD identified
    - Type 1 is a partial quantitative deficiency of vWF deficiency and accounts for 75% of all patients
    - Type 2 is a more pronounced qualitative deficiency and comprises almost all the remaining 25% of patients
      - Type 2 disease is further divided into 4 variants named 2A, 2B, 2M, 2N on the basis of identified phenotypes
    - Type 3 is characterized as a complete vWF deficiency and occurs very rarely
      - For type 3 vWD patients, their inherent Factor VIII levels are typically very low

Hemophilia – Indications

Drugs	Indications
	Factor VIII Products
antihemophilic factor VIII - recombinant (Advate)	• Control and prevention of bleeding episodes in adults and children with hemophilia A (classical hemophilia) • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for von Willebrand disease (vWD)
antihemophilic factor VIII – recombinant, PEGylated (Adynovate)	• Control and prevention of bleeding episodes in adults and adolescents 12 years and older with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant, single chain (Afstyla)	• Prevention and control of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – plasma derived (Alphanate)	• Control and prevention of bleeding episodes in hemophilia A • Surgical and/or invasive procedures in adult and pediatric patients with vWD in whom desmopressin is ineffective or contraindicated; it is not indicated for patients with severe vWD (type 3) undergoing major surgery
antihemophilic factor VIII – recombinant, FC fusion protein (Eloctate)	• Prevention and control of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant (Helixate FS)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children with hemophilia A and no preexisting joint damage • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A • Not indicated for vWD

Hemophilia – Indications

Drugs	Indications
Factor VIII Products (Continued)	
antihemophilic factor VIII – plasma derived (Hemofil M)	• Control and prevention of hemorrhagic episodes in hemophilia A • Not indicated for vWD
antihemophilic factor VIII – plasma derived (Humate-P)	• Treatment and prevention of bleeding in adults with hemophilia A • Treatment of spontaneous and trauma-induced bleeding episodes, and prevention of excessive bleeding during and after surgery for adults and pediatric patients with vWD; this applies to patients with severe and mild to moderate vWD where the use of desmopressin is known or suspected to be inadequate • Not indicated for the prophylaxis of spontaneous bleeding episodes in vWD
antihemophilic factor VIII – plasma derived (Koate DVI)	• Treatment of hemophilia A in which there is a demonstrated deficiency of activity of the plasma clotting Factor VIII to control or prevent bleeding episodes, or in order to perform emergency and elective surgery on individuals with hemophilia • Not approved for use in vWD
antihemophilic factor VIII – recombinant (Kogenate FS)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children with hemophilia A and reduce the risk of joint damage in children showing no preexisting joint damage • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant (Kovaltry)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management of bleeds in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – plasma derived (Monoclate-P)	• Treatment of hemophilia A • Not indicated or effective for vWD
antihemophilic factor VIII – recombinant (Novoeight)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD

Hemophilia – Indications

Drugs	Indications
Factor VIII Products (Continued)	
antihemophilic factor VIII – recombinant (Nuwiq)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative bleed management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant, porcine sequence (Obizur)	• Treatment of bleeding episodes in adults with acquired hemophilia A • Safety and efficacy have not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU • Not indicated for the treatment of congenital hemophilia A or vWD
antihemophilic factor VIII – recombinant (Recombinate)	• Control and prevention of hemorrhagic episodes in hemophilia A in adults and children • Perioperative management in patients with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant (Xyntha)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Not indicated for vWD
Factor IX Products	
coagulation factor IX – plasma derived (AlphaNine SD)	• Prevention and control of bleeding in patients greater than 16 years of age with Factor IX deficiency due to hemophilia B • AlphaNine SD contains low, non-therapeutic levels of Factors II, VII, and X, and is not indicated for the treatment of Factor II, VII, or X deficiencies • Not indicated for the treatment of hemophilia A patients with inhibitors to Factor VIII
coagulation factor IX – recombinant, FC fusion protein (Alprolix)	• Prevention and control of bleeding episodes in adults and children with Factor IX deficiency, hemophilia B • Perioperative management in adults and children with hemophilia B • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with Factor IX deficiency, hemophilia B • Not indicated for induction of immune tolerance therapy in patients with hemophilia B.
coagulation factor IX – plasma derived (Bebulin)	• Prevention and control of hemorrhagic episodes in adult hemophilia B patients • Not indicated for use in the treatment of Factor VII deficiency; no clinical studies have been conducted to show benefit from this product for treating deficiencies other than Factor IX deficiency

Hemophilia – Indications

Drugs	Indications
Factor IX Products (Continued)	
coagulation factor IX – recombinant (BeneFIX)	• Prevention and control of bleeding episodes in adults and pediatric patients with hemophilia B • Perioperative management in adults and pediatric patients with hemophilia B • Not indicated for the treatment of other factor deficiencies (e.g., Factors II, VII, VIII, and X), or the treatment of hemophilia A patients with inhibitors to Factor VIII
coagulation factor IX – recombinant, albumin fusion protein (Idelvion)	• Prevention and control of bleeding episodes in adults and children with hemophilia B • Perioperative management in adults and children with hemophilia B • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia B • Not indicated for induction of immune tolerance therapy in patients with hemophilia B.
coagulation factor IX – recombinant (Ixinity)	• Prevention and control of bleeding episodes in adults and pediatric patients 12 years of age or older with hemophilia B • Perioperative management in adults and pediatric patients with hemophilia B • Not indicated for the induction of immune tolerance therapy in patients with hemophilia B
coagulation factor IX – plasma derived (Mononine)	• Prevention and control of bleeding in Factor IX deficiency, also known as hemophilia B • Not indicated in the treatment or prophylaxis of hemophilia A in patients with inhibitors to Factor VIII • Not indicated for treatment of or reversal of coumadin-induced anticoagulation • Mononine contains non-detectable levels of Factors II, VII, and X and is, therefore, not indicated for replacement therapy of these clotting factors
coagulation factor IX – plasma derived (Profilnine SD)	• Prevention and control of bleeding in patients with Factor IX deficiency due to hemophilia B • Not indicated for use in the treatment of Factor VII deficiency
coagulation factor IX – recombinant (Rixubis)	• Prevention and control of bleeding episodes in adults and children with Factor IX deficiency, hemophilia B • Perioperative management in adults and children with hemophilia B • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with Factor IX deficiency, hemophilia B • Not indicated for induction of immune tolerance therapy in patients with hemophilia B.

Hemophilia – Indications

Drugs	Indications
Factor VIIa and Activated Prothrombin Complex Concentrate Products	
activated prothrombin complex - plasma derived (Feiba)	• Control and prevention of bleeding episodes in hemophilia A and hemophilia B patients with inhibitors • Perioperative management in hemophilia A and hemophilia B patients with inhibitors • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in hemophilia A and hemophilia B patients with inhibitors • Not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to factor VIII or factor IX
coagulation factor VIIa – recombinant (Novo Seven RT)	• Treatment of bleeding episodes in hemophilia A or B with inhibitors and in acquired hemophilia • Prevention of bleeding in surgical interventions or invasive procedures in hemophilia A or B with inhibitors and in acquired hemophilia • Treatment of bleeding episodes in congenital Factor VII (FVII) Deficiency • Prevention of bleeding in surgical interventions or invasive procedures in congenital FVII deficiency • Treatment of Glanzmann's Thrombasthenia with refractoriness to platelet transfusions with or without antibodies
Factor X and Factor XIII Products	
coagulation factor X - plasma derived (Coagadex)	• Control and prevention of bleeding episodes in adults and adolescents 12 years and older with heredity factor X deficiency • Perioperative management of bleeding in patients with mild heredity factor X deficiency
coagulation factor XIII – plasma derived (Corifact)	• Routine prophylactic treatment for adult and pediatric patients with congenital factor XIII deficiency • Perioperative management of surgical bleeding in adult and pediatric patients with congenital XIII deficiency
coagulation factor XIII A-subunit– recombinant (Tretten)	• Routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency • Not indicated for use in patients with congenital factor XIII B-subunit deficiency
Von Willebrand Products	
von Willebrand factor - recombinant (Vonvendi)	• Control and prevention of bleeding episodes in adults and children 18 years of age and older with von Willebrand disease
Von Willebrand factor/coagulation factor VIII complex –plasma derived (Wilate)	• For on-demand treatment and control of bleeding episodes in children and adults with vWD • Perioperative management of bleeding in children and adults with vWD • Not indicated for treatment of hemophilia A

Hemophilia – Dosing and Availability

Drugs	Manufacturer Recommended Starting Doses for Prophylaxis	Availability
Factor VIII Products		
antihemophilic factor VIII – recombinant (Advate)	• For children and adults; 20-40 IU/kg every other day (3 to 4 times a week) or every third day to maintain factor VIII trough levels greater than or equal to 1% • Adjust dosing based on patient's clinical response	• Single-dose vials of 250 IU, 500 IU, 1,000 IU, 1,500 IU, 2,000 IU, 3,000 IU, and 4,000 IU
antihemophilic factor VIII – recombinant, PEGylated (Adynovate)	• Adults and adolescents 12 years and older - 40-50 IU/kg 2 times a week • For children < 12 years, start with 55 IU/kg 2 times a week with maximum of 70 IU/kg • Adjust dosing based on patient's clinical response	• Single-dose vials of 250 IU, 500 IU, 750 IU, 1,000 IU, 1,500 IU, 2,000 IU, and 3,000 IU
antihemophilic factor VIII – recombinant, single chain (Afstyla)	• For children < 12 years; 30-50 IU/kg 2 to 3 times a week • For adults and adolescents 12 years and older; 20-50 IU/kg 2 to 3 times a week • Adjust dosing based on patient's clinical response	• Single-dose vials of 250 IU, 500 IU, 1,000 IU, 1,500 IU, 2,000 IU, 2,500 IU, and 3,000 IU
antihemophilic factor VIII – plasma derived (Alphanate)	• Dose (units) = body weight (kg) x desired FVIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL). • The dosing frequency should be determined by the type of bleeding episode and the recommendation of the physician.	• Single-dose vials in strengths of 250 IU, 500 IU, 1,000 IU, 1,500 IU, and 2,000 IU
antihemophilic factor VIII – recombinant, FC fusion protein (Eloctate)	• For children and adults; 50 IU/kg every 4 days • Adjust dosing based upon patient's clinical response • Dosing range based upon response may be adjusted within 25-65 IU/kg every 3 to 5 days • Doses of up to 80 IU/kg with greater frequency may be required for children < 6 years of age	• Single-use vials of 250 IU, 500 IU, 750 IU, 1,000 IU, 1,500 IU, 2,000 IU, 3,000 IU, 4,000 IU, 5,000 IU, and 6,000 IU with diluent
antihemophilic factor VIII – recombinant (Helixate FS)	• For children 15 years and younger; 25 IU/kg every other day • For adults 15 years and older; 25 IU/kg 3 times a week • Adjust dosing based on patient's clinical response	• Single-use glass vials in strengths of 250 IU, 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU
antihemophilic factor VIII – plasma derived (Hemofil M)	N/A	• Single-dose bottles in strengths of 250 IU, 500 IU, 1,000 IU, and 1,700 IU
antihemophilic factor VIII – plasma derived (Humate-P)	N/A	• Single-dose vials in strengths of 250 IU, 500 IU, and 1,000 IU of Factor VIII/vial and 600 IU, 1,200 IU, and 2,400 IU vWF:RCo/vial

Hemophilia – Dosing and Availability

Drugs	Manufacturer Recommended Starting Doses for Prophylaxis	Availability
Factor VIII Products (Continued)		
antihemophilic factor VIII – plasma derived (Koate DVI)	N/A	• Single-dose bottles in strengths of 250 IU, 500 IU, and 1,000 IU
antihemophilic factor VIII – recombinant (Kogenate FS)	• For children;25 IU/kg every other day • For adults; 25 IU/kg 3 times a week	• Single-use glass vials in strengths of 250 IU, 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU
antihemophilic factor VIII – recombinant (Kovaltry)	• For children < 12 years; 25-50 IU/kg 2 to 3 times a week or every other day based on individual requirements • For adults and adolescents 12 years and older; 20-40 IU/kg 2 to 3 times a week	• Single-use glass vials in strengths of 250 IU, 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU
antihemophilic factor VIII – plasma derived (Monoclate-P)	N/A	• Single-dose vials in strengths of 1,000 IU and 1,500 IU
antihemophilic factor VIII – recombinant (Novoeight)	• For children < 12 years of age: 20-50 IU/kg every other day or 20-60 IU/kg 3 times a week • For adults and children 12 years and older: 20-40 IU/kg every other day or 20-50 IU/kg 3 times a week	• Single-use glass vials in strengths of 250 IU, 500 IU, 1,000 IU, 1,500 IU, 2,000 IU, and 3,000 IU
antihemophilic factor VIII – recombinant (Nuwiq)	• For children < 12 years of age: 30-50 IU/kg every other day or 3 times a week • For adults and children 12 years and older: 30-40 IU/kg every other day • Adjust dosing based on patient's clinical response	• Single-use vials in strengths of 250 IU, 500 IU, 1,000 IU, 2,000 IU, 2,500 IU, 3,000 IU, and 4,000 IU
antihemophilic factor VIII – recombinant, porcine sequence (Obizur)	N/A	• Single-dose vials in strengths of 500 U
antihemophilic factor VIII – recombinant (Recombinate)	N/A	• Single-dose vials in the following strengths: 220 to 400 IU; 401 to 800 IU; 801 to 1,240 IU; 1,241 to 1,800 IU; and 1,801 IU to 2,400 IU
antihemophilic factor VIII – recombinant (Xyntha)	N/A	• Single-use vials and prefilled dual-chamber syringes (Solofuse) in strengths of 250 IU, 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU

Hemophilia – Dosing and Availability

Drugs	Manufacturer Recommended Starting Doses for Prophylaxis	Availability
Factor IX Products		
coagulation factor IX – plasma derived (AlphaNine SD)	N/A	• Single-dose vials of 500 IU, 1,000 IU, and 1,500 IU with diluent
coagulation factor IX – recombinant, FC fusion protein (Alprolix)	• Children & adults; 50 IU/kg once a week or 100 IU/kg once every 10 days	• Single-use vials of 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU with diluent
coagulation factor IX – plasma derived (Bebulin)	N/A	• Single-dose vials contain 200 to 1,200 IU and diluent
coagulation factor IX – recombinant (BeneFIX)	N/A	• Single-use vials contain 250 IU, 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU with diluent
coagulation factor IX – recombinant, albumin fusion protein (Idelvion)	• For children< 12 years of age: 40-55 IU/kg every 7 days • For adults and children 12 years and older: 25-40 IU/kg every 7 days. If well controlled, may switch to 50-75 IU/kg every 14 days	• Single-use vials of 250 IU, 500 IU, 1,000 IU, and 2,000 IU with diluent
coagulation factor IX – recombinant (Ixinity)	N/A	• Single-use vials contain 500 IU, 1,000 IU, 1,500 IU, 2,000 IU, and 3,000 IU with diluent • Multi-vial (2) Kit with 1,000 IU and 1,500 IU vials
coagulation factor IX – plasma derived (Mononine)	N/A	• Single-dose vials contain approximately 1,000 IU with diluent
coagulation factor IX – plasma derived (Profilnine SD)	N/A	• Single-dose vials of 500 IU, 1,000 IU, and 1,500 IU
coagulation factor IX – Recombinant (Rixubis)	• For patients < 12 years of age previously treated with Factor IX; 60-80 IU/kg twice a week • For patients 12 years and older previously treated with Factor IX; 40-60 IU/kg twice a week	• Single-use vials contain 250 IU, 500 IU, 1,000 IU, 2,000 IU, and 3,000 IU with diluent

Hemophilia – Dosing and Availability

Drugs	Manufacturer Recommended Starting Doses for Prophylaxis	Availability
Factor VIIa and Activated Prothrombin Complex Concentrate Products		
anti-inhibitor coagulant complex plasma derived (Feiba)	• 85 IU/kg every other day • Adjust dosing based on patient's clinical response • Not to exceed a single dose of 100 units/kg of body weight or a total daily dose of 200 units/kg body weight	• Single-dose vials of 500 U, 1,000 U, and 2,500 U with diluent
coagulation factor VIIa - recombinant (Novo Seven RT)	N/A	• Single-dose vials of 1 mg, 2 mg, 5 mg, and 8 mg with diluent
Von Willebrand Products		
von Willebrand factor – recombinant (Vonvendi)	N/A	• Single-dose vials in 2 vWF:RCo strengths: 650 IU (450-850 IU) and 1,000 IU (900-1,700 IU)
von Willebrand factor/coagulation factor VIII complex – plasma derived (Wilate)	N/A	• Single-dose vial in strengths of 500 IU vWF:RCo and 500 IU Factor VIII activities and 1,000 IU vWF:RCo and 1,000 IU Factor VIII activities

Hemophilia – Guidelines

- World Federation of Hemophilia, 2012 (Updated 2014)
  - The guidelines list the general principles of care for treatment of bleeding episodes including:
    - The prevention and treatment of bleeds with the specific factor concentrate for that patient's clotting deficiency
    - Treatment of active bleeds as soon as possible and preferably within a 2-hour window of onset
    - Help in teaching patients to recognize a bleeding aura which is often experienced prior to outward evidence of a bleed
    - The use of adjunctive therapies to help control bleeds
    - Including compression and cold therapy
    - Ensuring that patients seek experienced medical care, including a pediatric or adult hematologist and continuing care through a recognized hemophilia treatment center
    - Use of patient training and home therapy to treat non-life-threatening bleeding episodes
    - Comprehensive care plans that encourage and promote regular exercise to improve overall fitness while avoiding activities likely to cause trauma
    - Maintaining good oral health and regular appointments to monitor health status

  - Von Willebrand
    - Three main approaches for the treatment are:
      - Increasing plasma concentrations of vWF through stimulation with desmopressin (DDAVP)
      - Replacing vWF by using human plasma-derived viral inactivated concentrates
      - Promoting hemostasis by utilizing hemostatic agents with mechanisms other than increasing vWF
    - Regular prophylaxis for von Willebrand patients is seldom required

Hematological Agents - Misc : Antihemophilic Products

- **Current Limitation**
  - Therapeutic class carved out from Managed Medicaid plans
  - Center of excellent required
- **Recommendation:**
  - Continue current limitation

Hematological Agents - Misc : Antihemophilic Products

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the Hematological Agents : Antihemophilic Products listed on slide 27 as recommended."

Motion: Figueroa

2nd: Park

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Thrombopoiesis Stimulating Proteins

Hematopoietic Agents: Thrombopoietin (TPO) Receptor Antagonists

Overview of Disease State – Thrombopoiesis Stimulating Proteins

- Platelets are small, circulating cell particles that do not contain a nucleus. They are released into the bloodstream by megakaryocytes that reside in the bone marrow. Platelets function to maintain hemostasis by aggregating and forming platelet plugs at sites of injury to limit blood loss

- Thrombocytopenia
  - Defined as a platelet count of less than 100 x 10^9/L
  - Can result in bruising, bleeding, and fatal hemorrhaging
  - Causes include decreased bone marrow production of megakaryocytes, splenic sequestration of platelets, and increased destruction of platelets

- Thrombocytopenia related to myelosuppressive chemotherapy
  - Following chemotherapy, bone marrow production of megakaryocytes is impaired
  - For thrombocytopenia related to myelosuppressive chemotherapy, oprelvekin (Neumega) has been shown to prevent severe thrombocytopenia and reduce the need for platelet transfusions in patients receiving myelosuppressive chemotherapy
  - It is not indicated for primary prevention; Neumaga is indicated for patients who have experienced severe thrombocytopenia in a previous chemotherapy cycle

Overview of Disease State – Thrombopoiesis Stimulating Proteins

Immune Thrombocytopenia (ITP)

- Previously known as “Immune thrombocytopenic purpura” and “Idiopathic thrombocytopenic purpura”
- An immune-mediated disorder in which platelets are opsonized by autoreactive antibodies and prematurely destroyed by the reticuloendothelial system
- Primary ITP
  - Primary ITP is also defined by the length of time since diagnosis – newly diagnosed (less than three months), persistent (between three and 12 months), and chronic (more than 12 months)
  - Secondary causes of ITP include drug-induced, autoimmune diseases such as systemic lupus erythematosus (SLE), and viral infections such as human immunodeficiency virus (HIV) and Hepatitis C
  - Severe ITP, occurring at any time, indicates bleeding which requires treatment or the occurrence of new bleeding symptoms which requires additional treatment or increased dose to control bleeding
- In children
  - ITP is usually an acute, self-limiting disease that often occurs two to three weeks after a viral infection or immunization
  - Spontaneous remission in children typically occurs within two to eight weeks
- In adults
  - Many adult cases of ITP are diagnosed incidentally after a routine complete blood count (CBC)
  - Signs and symptoms of ITP are highly variable and range from asymptomatic with mild bruising or mucosal bleeding to frank hemorrhage from any site
  - Severity of ITP in adults is dependent on the presence of active bleeding; platelet count; patient age; patient’s lifestyle related to risk of bleeding; and presence of additional risk factors for bleeding, such as uremia or chronic liver diseases

Thrombopoiesis Stimulating Proteins – Indications

Drugs	Generic	Indications
eltrombopag (Promacta)		Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy Treatment of thrombocytopenia in patients with chronic hepatitis C (HCV) to allow the initiation and maintenance of interferon-based therapy • Eltrombopag should only be used in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding • Eltrombopag should not be used in an attempt to normalize platelet counts • Eltrombopag should be used only in patients with chronic hepatitis CHCV whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy • Safety and efficacy have not been established in combination with direct acting antiviral agents approved for treatment of chronic HCV genotype 1 infection
oprelvekin (Neumega)		Prevention of severe thrombocytopenia and reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia. Efficacy was demonstrated in patients who had experienced severe thrombocytopenia following the previous chemotherapy cycle. • Oprelvekin is not indicated following myeloablative chemotherapy
romiplostim (Nplate)		Treatment of thrombocytopenia in patients with chronic ITP who have failed to achieve an adequate response with corticosteroids, immunoglobulins, or splenectomy. • Romiplostim should only be used in patients with ITP whose degree of thrombocytopenia and clinical condition increases their risk for bleeding. • Romiplostim is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP. • Romiplostim should not be used in an attempt to normalize platelet counts

Thrombopoiesis Stimulating Proteins – Dosing and Availability

Drugs	Initial Dosing	Titration	Availability
eltrombopag (Promacta)	25 mg once daily for thrombocytopenia in patients with chronic hepatitis C and 50 mg once daily for chronic immune thrombocytopenia on an empty stomach given one hour before or two hours after a meal Lower dose recommended for patients with hepatic impairment and/or East Asian ancestry	Adjust the dose to achieve and maintain a platelet count ≥ 50 x 109/L as needed to reduce the risk for bleeding Dose adjustments are based on platelet count response Do not exceed a dose of 75 mg daily for chronic immune thrombocytopenia and 100 mg daily for thrombocytopenia in patients with chronic hepatitis C	12.5, 25, 50, 75 mg tablets
oprelvekin (Neumega)	50 mcg/kg daily as a single subcutaneous injection in the abdomen, thigh, hip or upper arm if not self injecting.	--	5 mg vial
romiplostim (Nplate)	1 mcg/kg (based on actual body weight) weekly given by subcutaneous injection. Syringes used for injection should have 0.01 mL graduations.	Adjust the weekly dose by increments of 1 mcg/kg until the patient achieves a platelet count ≥ 50 x 109/L as necessary to reduce the risk for bleeding; do not exceed a maximum weekly dose of 10 mcg/kg Median dose is 2 mcg/kg weekly Do not dose if platelet count >400 x 109/L.	250, 500 mcg vial

Thrombopoiesis Stimulating Proteins – Guidelines

International Consensus Report (2010) on Primary ITP

- The treatment goal of ITP is to provide a safe platelet count that prevents major bleeding rather than correcting the platelet count to normal levels
  - Treatment decisions depend on the presence or absence of bleeding, platelet count, and assessment of risk factors for bleeding
  - In adults, corticosteroids, particularly prednisone, continue to be first-line therapy for the treatment of ITP
    - Intravenous gammaglobulin (IVIG) infusions may induce a response faster than corticosteroids
    - Intravenous anti-RhO (D)/anti-D may be an effective alternative; however, these products cannot be used for Rh-negative or postsplenectomy patients
  - Although not approved for the treatment of ITP, second line therapies include azathioprine, cyclophosphamide, cyclosporine, danazol, dapsone, mycophenolate mofetil, rituximab, splenectomy, thrombopoietin agonists, and vinca alkaloids
  - Treatment for patients failing first and second-line therapies includes thrombopoietin receptor agonists which have sufficient data to support their use and other therapies which have minimal data to support their use and are considered to have potential for considerable toxicity

Thrombopoiesis Stimulating Proteins – Guidelines

- Management of Immune Thrombocytopenia, American Society of Hematology (ASH), 2011
  - For adults, treatment for a newly diagnosed patient is considered at a platelet count of $<30x10^9/L$
  - Treatment decisions should consider the presence and severity of bleeding, the rapidity of desired platelet count rise, and the possible adverse effects
  - In the management of adults with ITP, first line treatment includes longer courses of corticosteroids (such as prednisone 1 mg/kg orally for 21 days then tapered off) over shorter courses of corticosteroids or IVIG as first line treatment
    - IVIG may be used with corticosteroids when a more rapid increase in platelet count is necessary
    - Either IVIG or anti-D (in appropriate patients) may be used as a first line therapy if corticosteroids are contraindicated
    - If IVIG is used, the dose should initially be 1 g/kg as a one-time dose. IVIG may be repeated if necessary
  - Recommend splenectomy for patients who are unresponsive to or relapse after initial corticosteroid therapy
    - Thrombopoietin receptor agonists may be considered
      - For patients at risk for bleeding who have failed at least one other therapy and who relapse after splenectomy or have a contraindication to splenectomy
      - In patients at risk for bleeding who have not had a splenectomy and who have failed one line of therapy such as corticosteroids or IVIG
    - For adult patients after splenectomy, no treatment is recommended if the platelet count exceeds $30x10^9/L$

Hematopoietic Agents : Thrombopoietin (TPO) Receptor Agonists

- **Current Limitation:**
  - Varies based on plan
- **Recommendation:**
  - All Thrombopoietin Receptor Agonists are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
  - All non-preferred products require a trial of two preferred products with the same indication and different active ingredients before a non-preferred product will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Hematopoietic Agents : Thrombopoietin (TPO) Receptor Agonists

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the Thrombopoietin Receptor Agonists listed on slide 36 as recommended."

Motion: Flatebo

2nd: Brown

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Immune Globulins

Passive Immunizing and Treatment Agents: Combinations
Passive Immunizing Treatment Agents: Immune Serums

Overview of Disease State – Immune Globulins

- Primary immunodeficiencies are inherited disorders of the immune system that predispose an individual to an increased rate and severity of infections, as well as other possible sequelae such as autoimmune diseases and certain malignancies
- Primary immune deficiencies are categorized as humoral (or antibody) deficiencies, cellular deficiencies, innate immune disorders, or a combination of deficiencies
  - The hallmark of humoral immunodeficiency is recurrent bacterial infections of the upper and lower respiratory tract
  - Deficiency in the body's ability to fight infections through the humoral immune process predisposes an individual to significant morbidity and possible death from bacterial infections
- Under normal circumstances, the body produces a variety of immunoglobulin (e.g., antibody) isotypes – Immune globulin A (IgA), Immune globulin G (IgG), and Immune globulin M (IgM)
  - IgG deficiencies, in particular, increase an individual's susceptibility to a host of infections
  - Primary antibody deficiencies, which account for approximately 50% of the diseases categorized under the primary immunodeficiency disease (PIDD) umbrella, have been characterized based on the presence or absence of B cells, as well as the quantity and quality of an individual's IgG pool
  - Low numbers of immune globulin and/or antibodies of substandard quality require therapeutic intervention through the delivery of exogenous immune globulin preparations
  - Despite such varied phenotypic presentations, the continued hallmark of treatment for these diseases is the supplementation of immune globulin via either intravenous or subcutaneous means
- In addition to its use in PIDD, exogenous immune globulin product has been FDA approved for use in:
  - Certain neurologic disorders (multifocal motor neuropathy [MMN], chronic inflammatory demyelinating polyneuropathy [CIDP])
  - Other diseases (immune thrombocytopenic purpura [ITP], Kawasaki syndrome, B-cell chronic lymphocytic leukemia)

Immune Globulins – Indications

Drugs	Generic	Indications
Intravenous		
Bivigam		▪ Primary humoral immunodeficiency
Carimune NF, Nanofiltered		▪ Primary humoral immunodeficiency ▪ Immune thrombocytopenic purpura
Flebogamma DIF 5% and 10%,		▪ Primary (inherited) immunodeficiency ▪ Chronic primary immune thrombocytopenia (10% only)
Gammagard S/D		▪ Primary humoral immunodeficiency ▪ Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia ▪ Chronic immune thrombocytopenic purpura ▪ Prevention of coronary artery aneurysms associated with Kawasaki syndrome
Gammaplex 5% and 10%,		▪ Primary humoral immunodeficiency ▪ Chronic immune thrombocytopenic purpura
Octagam 5% and 10%,		▪ Primary humoral immunodeficiency (5% only) ▪ Chronic immune thrombocytopenic purpura (10% only)
Privigen		▪ Primary humoral immunodeficiency ▪ Chronic immune thrombocytopenic purpura ▪ Chronic inflammatory demyelinating polyneuropathy (Limitation of use: maintenance therapy has not been studied > 6 months)
Intravenous or Subcutaneous		
Gammagard Liquid		▪ Primary humoral immunodeficiency ▪ Multifocal motor neuropathy
Gammaked		▪ Primary humoral immunodeficiency ▪ Idiopathic thrombocytopenic purpura (IV use only) ▪ Chronic inflammatory demyelinating polyneuropathy (IV use only)
Gamunex-C		▪ Primary humoral immunodeficiency ▪ Idiopathic thrombocytopenic purpura (IV use only) ▪ Chronic inflammatory demyelinating polyneuropathy (IV use only)

Immune Globulins – Indications

Drugs	Generic	Indications
Subcutaneous		
Cuvitru		▪ Primary immune deficiency
Hizentra		▪ Primary immune deficiency ▪ Maintenance therapy in patients with chronic inflammatory demyelinating polyneuropathy
immune globulin 10%/recombinant human hyaluronidase Hyqvia		▪ Primary immune deficiency

Immune Globulins – Dosing and Availability

Drug	Diagnosis	Dose	Availability
General Guidance, intravenous (IV)	▪ Use caution in pre-existing renal insufficiency; ensure patients are not volume depleted ▪ Administer at minimum infusion rate practical for patients at risk of renal dysfunction or thrombotic event		
Bivigam, IV	▪ PI	▪ 300–800 mg/kg every 3–4 weeks	▪ 10% vial, 50 mL ▪ 10% vial, 100 mL ▪ Not made with natural rubber latex
Carimune NF, Nanofiltered, IV	▪ PI	▪ 400–800 mg/kg every 3–4 weeks	▪ 6 gm vial, lyophilized ▪ 12 gm vial, lyophilized
	▪ ITP	▪ Induction therapy: ▪ 400 mg/kg on 2–5 consecutive days	
		▪ Only 2 consecutive doses are required if the initial platelet count response to first 2 doses is adequate (30–50,000/µL) ▪ For chronic ITP, if platelet counts fall to < 30,000/µL or there is significant bleeding, patient may be given a 400 mg/kg dose as a single infusion; dose may be increased to 800–1,000 mg/kg if response is inadequate	
	▪ In PI treatment naive patients, first dose must be given as a 3% immunoglobulin solution; subsequent doses may be given at higher concentrations if tolerated ▪ Administer at minimum infusion rate practical for patients at risk of renal dysfunction or thrombotic events; do not infuse at a rate greater than 2 mg/kg/min		
Flebogamma DIF, IV	▪ PI	▪ 300–600 mg/kg every 3–4 weeks	▪ 5% vial, 10 mL ▪ 5% vial, 50 mL ▪ 5% vial, 100 mL ▪ 5% vial, 200 mL ▪ 5% vial, 400 mL ▪ 10% vial, 50 mL ▪ 10% vial, 100 mL ▪ 10% vial, 200 mL
	▪ ITP	▪ 1 gm/kg daily for 2 consecutive days	

Immune Globulins – Dosing and Availability

Drug	Diagnosis	Dose	Availability
Gamunex-C, IV Gammaked IV	▪ PI	▪ 300–600 mg/kg every 3–4 weeks	▪ 1 gm/10 mL vial ▪ 2.5 gm/25 mL vial ▪ 5 gm/50 mL vial ▪ 10 gm/100 mL vial ▪ 20 gm/200 mL vial ▪ Gamunex-C only: 40 gm/400 mL
	▪ ITP	▪ 2 gm/kg	
	▪ CIDP	Loading dose: ▪ 2 gm/kg Maintenance: ▪ 1 gm/kg every 3 weeks	
	▪ Contains glycine to manage isotonicity		
Octagam, IV	▪ PI	▪ 5%: 300–600 mg/kg every 3–4 weeks	▪ 5% vial, 20 mL ▪ 5% vial, 50 mL ▪ 5% vial, 100 mL ▪ 5% vial, 200 mL ▪ 5% vial, 500 mL
	▪ chronic ITP	▪ 1 g/kg for 2 consecutive days	▪ 10% bottle, 20 mL ▪ 10% bottle, 50 mL ▪ 10% bottle, 100 mL ▪ 10% bottle, 200 mL
Privigen, IV	▪ PI	▪ 200–800 mg/kg every 3–4 weeks	▪ 10% vial, 50 mL ▪ 10% vial, 100 mL ▪ 10% vial, 200 mL ▪ 10% vial, 400 mL
	▪ chronic ITP	▪ 1 g/kg for 2 consecutive days	
	▪ ITP	▪ 1 gm/kg for 2 consecutive days	
Cuvitru, SC	▪ PI	▪ Dose should be initially individualized based on pharmacokinetics and clinical response and subsequently by serum IgG trough levels (see prescribing information for details; administration frequency ranges from daily up to every 2 weeks Multiply: ▪ Previous IVIG dose (in grams) x 1.3; then divide by the number of weeks between intravenous doses; provides initial weekly dose, then adjust by desired frequency; initiate 1 week following prior IVIG dose	▪ 20% vial, 5 mL ▪ 20% vial, 10 mL ▪ 20% vial, 20 mL ▪ 20% vial, 40 mL ▪ Room temperature or refrigerated ▪ Latex-free

Immune Globulins – Dosing and Availability

Drug	Disease	Dose	Availability
SUBCUTANEOUSLY (SC) ADMINISTERED PRODUCTS			
Gammagard Liquid, SC	▪ PI	Multiply: ▪ Previous IVIG dose (in grams) x 1.37 then divide by the number of weeks between intravenous doses	▪ 10% vial, 10 mL ▪ 10% vial, 25 mL ▪ 10% vial, 50 mL ▪ 10% vial, 100 mL ▪ 10% vial, 200 mL ▪ 10% vial, 300 mL
Gamunex-C, SC Gammaked, SC	▪ PI	▪ Multiply previous IGIV dose (in grams) x 1.37 then divide by the number of weeks between intravenous doses	▪ 1 gm / 10 mL vial ▪ 2.5 gm / 25 mL vial ▪ 5 gm / 50 mL vial ▪ 10 gm / 100 mL vial ▪ 20 gm / 200 mL vial Gamunex-C only: • 40 gm/400 mL vial
	▪ May not be administered SC for ITP or CIDP		
Hizentra, SC	Initial Weekly Dose: ▪ (Previous IVIG dose [in grams]/ Number of weeks between IVIG doses) x 1.37 Additional notes: ▪ Hizentra can be administered at regular intervals from daily up to every 2 weeks (biweekly) ▪ Administer first dose 1 week after receiving a regularly scheduled IVIG infusion ▪ Hizentra may be administered after the patient has received IVIG infusions at regular intervals for at least 3 months ▪ Provided the total weekly dose is maintained, any dosing interval from daily up to biweekly may be used for biweekly dosing, multiply the calculated Hizentra weekly dose by 2 ▪ For frequent dosing (2 to 7 times per week), divide the calculated weekly dose by the desired number of times per week (e.g., for 3 times per week dosing, divide weekly dose by 3) Infuse via an infusion pump ▪ Rotate administration sites weekly (abdomen, thighs, upper arms, and/or lateral hip); may use up to 4 injection sites simultaneously or up to 12 sites consecutively per infusion; minimum 2 inches between sites ▪ Infusion volume – for the first infusion, up to 15 mL per injection site; this may be increased to 20 mL per site after the fifth infusion and to a maximum of 25 mL per site as tolerated ▪ Infusion rate – for the first infusion, up to 15 mL/hr per site; this may be increased, to a maximum of 25 mL/hr Must NOT be administered intravenously		▪ 1 gm/5 mL vial ▪ 2 gm/10 mL vial ▪ 4 gm/20 mL vial ▪ 10 gm/50 mL vial ▪ Single-use, tamper-evident vial ▪ Preservative-free; latex-free ▪ Room temperature

Immune Globulins – Dosing and Availability

<table>
<tr><th>Drug</th><th>Dose</th><th>Availability</th></tr>
<tr>
<td>Hyqvia, SC</td>
<td>
Dosing:
For patients previously treated with another IgG treatment, administer the first dose approximately 1 week after the last infusion of their previous treatment.
Initial Treatment Interval/Ramp-up Schedule:
<table>
<tr><th>Week</th><th>Infusion</th><th>Dose/Interval</th><th>Example: 30 grams/4 weeks</th></tr>
<tr><td>1</td><td>1st infusion</td><td>1-week-dose</td><td>7.5 grams</td></tr>
<tr><td>2</td><td>2nd infusion</td><td>2-week-dose</td><td>15 grams</td></tr>
<tr><td>3</td><td colspan="3">No Infusion</td></tr>
<tr><td>4</td><td>3rd infusion</td><td>3-week-dose</td><td>22.5 grams</td></tr>
<tr><td>5</td><td colspan="3">No Infusion</td></tr>
<tr><td>6</td><td colspan="3">No Infusion</td></tr>
<tr><td>7</td><td>4th infusion (if required)</td><td>4-week-dose</td><td>30 grams</td></tr>
</table>
For patients switching from Immune Globulin Intravenous (IGIV):
▪ Administer Hyqvia at the same dose and frequency as the previous intravenous treatment, after the initial dose ramp-up
For patients naïve to IgG treatment or switching from another subcutaneous Immune Globulin (IGSC):
▪ Administer Hyqvia at 300 to 600 mg/kg at 3 to 4 week intervals, after initial ramp up
Administration:
▪ Hyqvia should be administered by a healthcare professional, caregiver or self-administered by the patient after appropriate training
▪ Infusion requires an infusion pump meeting flow rate specifications and a subcutaneous 24-gauge needle set labeled for high flow rates
▪ Suggested sites for infusion are the abdomen and thighs; if 2 infusion sites are used, the 2 infusion sites should be on opposite sides of the body
▪ The 2 components must be infused sequentially, beginning with the Recombinant Human Hyaluronidase and then infusing the full dose of Immune Globulin 10% through the same subcutaneous needle set within approximately 10 minutes of the Recombinant Human Hyaluronidase infusion
▪ Rate of infusion:
▪ Administer the Recombinant Human Hyaluronidase at an initial rate of approximately 1 to 2 mL per minute
</td>
<td>
- Dual vial unit of 2 single use vials; 1 vial containing immune globulin 10% and 1 vial containing recombinant human hyaluronidase

- 2.5 gm (25 mL) IG/200 units (1.25 mL) hyaluronidase

- 5 gm (50 mL) IG/400 units (2.5 mL) hyaluronidase

- 10 gm (100 mL) IG/800 units (5 mL) hyaluronidase

- 20 gm (200 mL) IG /1,600 units (10 mL) hyaluronidase
</td>
</tr>
</table>

Immune Globulins – Guidelines

- American Academy of Allergy, Asthma, and Immunology (AAAAI), 2011
  - Released a list of 8 guiding principles to support the safe and effective use of therapeutic immunoglobulin

Principles	Description
Indication	IVIG is FDA indicated for use in primary immunodeficiency where antibody production is absent or deficient
Diagnoses	Primary immunodeficiency has varied phenotypic manifestations. IVIG is indicated and recommended for the following clinical situations: A. Primary immune defects with absent B cells B. Primary immune defects with hypogammaglobulinemia and impaired specific antibody production C. Primary immune defects with normogammaglobulinemia and impaired specific antibody production
Frequency of Treatment	Once a diagnosis is confirmed, interruption of treatment places the patient at significant risk IVIG administration should occur at every 3 to 4 week intervals to ensure adequate coverage Due to patient-specific factors, shorter intervals may need to be considered
Dose	IVIG indicated for PI is supported by initial starting doses of 400 to 600 mg/kg every 3 to 4 weeks; alternate regimens are not supported by clinical literature
IgG Trough Levels	Interpretations of trough levels are only applicable in a subset of patients whose condition is characterized by low quantities of IgG levels For patients with sufficient quantities of IgG but who have impaired quality, trough levels are not correlated to clinical benefit Trough levels, as a rule, should be maintained above 500 mg/dL
Site of Care	Clinical characteristics and stability of the patient within a particular regimen should guide the decision for where IVIG is administered
Route	The use of the subcutaneous (SC) versus intravenous (IV) route to administer immunoglobulin therapy relies on a variety of patient characteristics. Some benefit of SC administration may be afforded to patients with poor venous access, as well as those with difficult to control adverse reactions using the IV route
Product	IVIG is not an interchangeable product Product selection relies heavily on clinical discretion to match the appropriate product to the patient while considering various patient factors, including comorbidities

Immune Globulins – Guidelines

- AAAAI and Clinical Immunology Society both support the use of individualized patient characteristic considerations and direct physician consultation in all situations of product selection
  - Selection of product is largely a function of matching patient characteristics with product properties

- Immune globulin product selection should be guided by patient-specific characteristics
  - The route of administration is an important consideration and can impact product selection
    - With the availability of both intravenously- and subcutaneously-administered products, physicians have a broader repertoire from which to choose for their patients
    - The subcutaneous route is as efficacious as the intravenous route for the treatment of primary immunodeficiencies and may be useful in patients who have experienced or are at an increased risk for complications related to the intravenous immune globulin therapy

Passive Immunizing and Treatment Agents : IVIG

- Passive Immunizing and Treatment Agents : Immune Serums
- Passive Immunizing and Treatment Agents : Combinations

Passive Immunizing and Treatment Agents : IVIG

- **Current Limitation**
  - Varies based on plan
- **Recommendation**
  - All Passive Immunizing and Treatment Agents : IVIG products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
  - All non-preferred products require a trial of two preferred products with the same indication before a non-preferred product will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Passive Immunizing and Treatment Agents : IVIG

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the Passive Immunizing and Treatment Agents : IVIG drug class listed on slide 49 as recommended."

Motion: Buccola

2nd: Park

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Growth Factors

Endocrine and metabolic agents: Insulin-like growth factors
Endocrine and metabolic agents: Growth hormone releasing hormones (GHRH)

Overview of Disease State – Growth Factors

- Growth hormone insensitivity or insulin-like growth factor-1 (IGF-1) deficiency refers to a variety of disorders characterized by the resistance to growth hormone
  - Growth hormone insensitivity can be defined by a deficiency in the production of growth hormone or peripheral action of IGF-1 on linear growth
  - Severe primary IGF-1 deficiency is due to a mutation of the growth hormone receptor or post-growth hormone receptor signaling
  - Severe primary IGF-1 deficiency is also characterized by the development of growth hormone inactivating antibodies in pediatric patients with growth hormone gene deletion
    - Patients are considered to have severe primary IGF-1 deficiency when the following criteria are met: height standard deviation score ≤ -3, basal IGF-1 standard deviation score ≤ -3, and normal or elevated growth hormone

- HIV Lipodystrophy
  - Soon after combination antiretroviral therapy was found effective in treating HIV infected patients, adverse side effects from the medications were reported, including metabolic changes, morphological abnormalities and lipodystrophy
  - HIV lipodystrophy is found in patients on highly active anti-retroviral therapy (HAART)
  - Patients with HIV lipodystrophy were described as having a loss of subcutaneous fat in limbs, face, and buttocks and an accumulation of fat in other areas of the body including the abdominal viscera
  - Patients who have increased visceral abdominal fat and waist circumference are at an increased risk for metabolic syndrome, cardiovascular disease, atherosclerosis, and diabetes mellitus

Growth Factors – Indications

Drugs	Generic	Indications
mecasermin [rDNA origin] injection (Increlex)		Treatment for growth failure in children with severe primary IGF-1 deficiency or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH
tesamorelin (Egrifta)		Growth hormone releasing factor (GRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy

Growth Factors – Dosing and Availability

Drugs	Dosage	Availability
mecasermin [rDNA origin] injection (Increlex)	Recommended dose: 0.04 to 0.08 mg/kg twice daily given subcutaneously If tolerated well after 1 week, the dose may be increased by 0.04 mg/ kg per dose to a maximum of 0.12 mg/kg given twice daily	Solution for injection: 40 mg/vial (10 mg per mL)
tesamorelin (Egrifta)	Recommended dose: 2 mg injected subcutaneously once daily	Lyophilized powder for injection: 1 mg tesamorelin/vial Diluent (sterile water for injection, USP 10 ml)

Growth Factors – Guidelines

- Severe IGF-1 Deficiency/Growth Hormone Gene Deletion
  - Increlex is the only available product approved for the indication of long-term treatment of growth failure in pediatric patients with severe primary IGF-1 deficiency or with growth hormone gene deletion with development of neutralizing antibodies to growth hormone
  - Patients with diagnoses that are not growth hormone deficient and will not respond well to exogenous growth hormone
  - Likewise, mecasermin (Increlex) should not be used as a substitute for patients who require growth hormone therapy
  - Increlex should not be used in patients with secondary forms of IGF-1 deficiency and all thyroid and nutritional issues should be corrected prior to initiating Increlex therapy
  - Increlex should not be used for weight loss management

- HIV Lipodystrophy
  - Recombinant human growth hormone (rhGH) has been used with success in patients with AIDS-related wasting syndrome since it has been shown to improve muscle mass
  - However, studies have shown rhGH causes a reduction in visceral adiposity but supra-physiologic levels of IGF-1 and symptoms of excess growth hormone occurred causing treatment cessation
  - Egrifta offers a specific treatment option for the reduction of excessive abdominal fat in HIV patients with lipodystrophy as it appears to target the visceral fat compartment with little effect on subcutaneous fat or fat in the limbs

Endocrine And Metabolic Agents : Insulin-like Growth Factors (Increlex)

Recommendation/Policy:

- Diagnosis of severe primary insulin-like growth factor 1 (IGF-1) deficiency **OR** growth hormone (GH) gene deletion (not growth hormone-deficient short stature) with neutralizing antibodies to GH; **AND**
- Less than (<) 18 years of age; **AND**

Endocrine And Metabolic Agents : Insulin-like Growth Factors (Increlex)

Recommendation Continued:

- **ALL** of the following:
  - Height standard deviation score ≤ -3.0; **AND**
  - Basal IGF-1 standard deviation score ≤ -3.0; **AND**
  - Normal or elevated growth hormone (GH), [serum growth hormone level of ≥ 10ngm/mL to at least TWO stimuli (insulin, levodopa, arginine, clonidine, or glucagon)]; **AND**
  - Evidence of non-closure of the epiphyseal plate; **AND**
  - Bone age of < 16 years old (male) OR < 14 years old (female); **AND**
  - Normal thyroid function (TSH in the range of 0.5 – 6 uU/mL); **AND**

Endocrine And Metabolic Agents : Insulin-like Growth Factors (Increlex)

Recommendation Continued:

- Prescribed by or in consultation with a specialist in endocrinology or nephrology; **AND**
- Dose does not to exceed 0.24 mg/kg/day; **AND**
- **NONE** of the following:
  - Malnourished (BMI < 18, where BMI=Weight(kg)/Height2(m)); **OR**
  - Active or suspected neoplasia (i.e. cancer); **OR**
  - Closed epiphyses; **OR**
  - Less than (<) 2 years of age

Endocrine And Metabolic Agents : Insulin-like Growth Factors (Increlex)

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for Increlex listed on slides 56-58 as recommended."

Motion: Schwilke

2nd: Storhaug

Endocrine and Metabolic Agents : Growth Hormone Releasing Hormones (GHRH)

(Egrifta)

Recommendation:

- Diagnosis of HIV-associated lipodystrophy; **AND**
- Excess accumulation of visceral abdominal fat due to HIV-associated lipodystrophy with the following gender-specific measures:
  - For Males:
    - Waist circumference greater than (>) 37.4 inches; **AND**
    - Waist-to-hip ratio greater than (>) 0.94
  - For Females:
    - Waist circumference greater than (>) 37 inches; **AND**
    - Waist-to-hip ratio greater than (>) 0.88

Endocrine And Metabolic Agents : Growth Hormone Releasing Hormones (GHRH)

(Egrifta)

Recommendation Continued:

- Documentation the excess accumulation of abdominal fat has impaired function, such as significantly limiting instrumental activities of daily living; **AND**
- Tried and failed a comprehensive diet and exercise program with physician and dietician involvement for at least 6 months, with patient compliance documented; **AND**
- Greater than or equal to (≥) 18 years of age or documentation of closed epiphyses; **AND**
- Currently receiving and adherent to antiretroviral therapy; **AND**

Endocrine And Metabolic Agents : Growth Hormone Releasing Hormones (GHRH)

(Egrifta)

Recommendation Continued:

- Dose does not exceed 2mg per day; **AND**
- Patient does NOT have any of the following:
  - Active malignancy; **OR**
  - Pregnancy; **OR**
  - Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism or pituitary tumor/surgery, head irradiation or head trauma

Endocrine And Metabolic Agents : Growth Hormone Releasing Hormones (GHRH)

(Egrifta)

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for Egrifta listed on slides 60-62 as recommended."

Motion: Figueroa

2nd: Lee

Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Iron, Parenteral

Hematopoietic Agents: Hematopoietic Mixtures
Hematopoietic Agents: Iron

Overview of Disease State – Iron, Parenteral

- Iron deficiency anemia is very common in chronic kidney disease (CKD) and may be associated with decreased absorption of iron from the gastrointestinal tract, limiting the usefulness of oral iron replacement
- Approximately 10 million people are iron deficient in the United States, including 5 million who have iron deficiency anemia
  - 30%–50% of anemia in children and other groups is caused by iron deficiency
- Iron deficiency anemia signs and symptoms may include:
  - Extreme fatigue
  - Weakness
  - Pale skin
  - Chest pain, fast heartbeat or shortness of breath
  - Headache, dizziness or lightheadedness
  - Cold hands and feet
  - Inflammation or soreness of your tongue
  - Brittle nails
  - Unusual cravings for non-nutritive substances, such as ice, dirt or starch
  - Poor appetite, especially in infants and children with iron deficiency anemia

Iron, Parenteral – Indications

Drugs	Generic	Indications
ferric carboxymaltose (Injectafer) MWt = 150,000 Da		Iron deficiency anemia in adult patients: ▪ Who have intolerance to oral iron or have had unsatisfactory response to oral iron ▪ Who have non-dialysis dependent CKD
ferric pyrophosphate citrate (Triferic) MWt = 1,313 Da		Replacement of iron to maintain hemoglobin in adult patients with hemodialysis- dependent CKD (HDD-CKD) ▪ Not intended for use in patients receiving peritoneal dialysis ▪ Has not been studied in patients receiving home hemodialysis
ferumoxytol (Feraheme) MWt = 750,000 Da		Iron deficiency anemia in adult patients: ▪ Who have CKD ▪ Who have intolerance to oral iron or have had an unsatisfactory response to oral iron
iron dextran (DexFerrum) MWt = 265,000 Da		Iron deficiency in adults and children in whom oral therapy is unsatisfactory or impossible ▪ Not recommended in children less than 4 months of age ▪ For IV injection only
iron dextran (InFeD) MWt = 165,000 Da InFeD		Iron deficiency in adults and children in whom oral therapy is unsatisfactory or impossible ▪ Not recommended in children < 4 months of age ▪ Do not use in anemia not related to iron deficiency ▪ For IV or IM injection InFeD [package insert]. Morristown, NJ; Watson; June 2017.
iron sucrose (Venofer) MWt = 34,000 to 60,000 Da		Iron deficiency anemia in patients with CKD
sodium ferric gluconate complex (Ferrlecit) MWt = 289,000 to 440,000 Da		Iron deficiency anemia in adult and pediatric patients age six years and older with CKD who are undergoing chronic hemodialysis and receiving supplemental epoetin

Iron, Parenteral – Dosing and Availability

Drugs	Dosage	Availability
ferric carboxymaltose (Injectafer) MWt = 150,000 Da	For patients weighing ≥ 50 kg (110 lb): ▪ Administer in 2 doses separated by at least 7 days; give each dose as 750 mg for a total cumulative dose of 1,500 mg of iron per course ▪ For patients weighing < 50 kg (110 lb): ▪ Administer in 2 doses separated by at least 7 days and give each dose as 15 mg/kg body weight Injectafer treatment may be repeated if iron deficiency anemia reoccurs Administration is given intravenously (IV), either as an undiluted slow IV push or by infusion	Single-dose vials: ▪ 750 mg iron in 15 mL ▪ (50 mg/mL) No preservative
ferric pyrophosphate citrate (Triferic) MWt = 1,313 Da	▪ Dilute ampules (either strength) or powder packet in bicarbonate concentrate used for the generation of hemodialysate to achieve a concentration of iron in the final hemodialysate of 2 micromolar (110 mcg/L); resulting solution should be used within 24 hours of preparation ▪ Administer to patients at each dialysis procedure for as long as patients are received maintenance hemodialysis therapy for CKD	Ampules of solution for dilution in bicarbonate concentrate: ▪ 27.2 mg iron/5 mL (5.44 mg/mL) ▪ 272 mg iron/50 mL (5.44 mg/mL) ▪ Powder for dilution in bicarbonate concentrate: ▪ 272 mg of iron per packet
ferumoxytol (Feraheme) MWt = 750,000 Da	▪ Administered as an initial 510 mg IV injection followed by a second 510 mg injection 3 to 8 days later; administer as an IV infusion in 50 mL to 200 mL NaCl or D5W over ≥ 15 minutes while patient is in a reclined or semi-reclined position, and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions; monitor for ≥ 30 minutes; allow ≥ 30 minutes between administration of other medications with the potential to cause similar adverse reactions ▪ In hemodialysis patients, inject at least 1 hour after initiation of dialysis and when blood pressure is stable ▪ Repletion usually takes 2 sessions to complete	Single-dose vials: ▪ 510 mg in 17 mL ▪ (30 mg/mL) No preservative Use immediately, but may be stored at controlled room temperature for up to 4 hours

Iron, Parenteral – Dosing and Availability

Drugs	Dosage	Availability
iron dextran (DexFerrum) MWt = 265,000 Da	▪ For iron deficiency anemia or blood loss: total dosage required for hemoglobin restoration and iron stores replacement is estimated using dosing tables or by calculation ▪ Test dose prior to first dose: 0.5 mL IV over greater than or equal to 5 minutes ▪ Then individual doses of ≤ 2 mL IV may be given daily until the total required dose is achieved; Administer undiluted at a rate of ≤ 50 mg/minute; daily dose not to exceed: 25 mg for infants < 5 kg; 50 mg for children < 10 kg; and 100 mg for those greater than 10 kg	Single-dose vials: ▪ 50 mg in 1 mL, 100 mg in 2 mL ▪ (50 mg/mL) No preservative
iron dextran (InFeD) MWt = 165,000 Da InFeD	▪ For iron deficiency anemia or blood loss: Total dosage required for hemoglobin restoration and iron stores replacement is estimated using dosing tables or by calculation ▪ Intravenous: ▪ Test dose prior to first dose: 0.5 mL IV over ≥ 30 seconds; monitor patient ≥ 60 minutes prior to administering therapeutic dose ▪ Then individual doses of ≤ 2 mL IV may be given daily until the total required dose is achieved; Administer undiluted at a rate of ≤ 50 mg/minute ▪ Intramuscular (IM): ▪ Test dose prior to first dose: 0.5 mL IM in the upper outer quadrant of the buttock; monitor patient ≥ 60 minutes prior to administering therapeutic dose ▪ Daily dose not to exceed: 25 mg for infants < 5 kg; 50 mg for < 10 kg; and 100 mg for those ≥ 10 kg until the calculated total amount required has been achieved	Single-dose vials: ▪ 100 mg in 2 mL ▪ (50 mg/mL) No preservative

Iron, Parenteral – Dosing and Availability

Drugs	Dosage	Availability
iron sucrose (Venofer) MWt = 34,000 to 60,000 Da	▪ Administer by slow IV injection or by infusion ▪ Adult CKD patients on hemodialysis: 100 mg undiluted IV injection over 2 to 5 minutes or diluted in ≤ 100 mL 0.9% NaCl over ≥ 15 minutes ▪ Adult CKD not on dialysis: 200 mg undiluted IV injection over 2 to 5 minutes or 200 mg diluted in ≤ 100 mL 0.9% NaCl over 15 minutes ▪ Adult CKD patients on peritoneal dialysis: infuse 300 mg over 1.5 hours for 2 doses, 14 days apart, followed 14 days later by a single infusion of 400 mg over 2.5 hours; Dilute in ≤ 250 mL 0.9% NaCl ▪ Pediatric (2 years and older) CKD patients on hemodialysis for iron maintenance treatment: infuse 0.5 mg/kg (maximum 100 mg per dose) every 2 weeks for 12 weeks undiluted by IV injection over 5 minutes or diluted in 25 mL 0.9% NaCl over 5 to 60 minutes ▪ Pediatric (2 years and older) CKD patients on peritoneal dialysis or not on dialysis who are on erythropoietin therapy for iron maintenance treatment: infuse 0.5 mg/kg (maximum 100 mg per dose) every 4 weeks for 12 weeks undiluted by IV injection over 5 minutes or diluted in 25 mL 0.9% NaCl over 5 to 60 minutes	Single-dose vials: ▪ 50 mg in 2.5 mL, 100 mg in 5 mL, 200 mg in 10 mL ▪ (20 mg/mL) No preservative
sodium ferric gluconate complex (Ferrlecit) MWt = 289,000 to 440,000 Da	▪ Adult: 125 mg (10 mL) per dialysis session; administer undiluted by slow IV injection (rate ≤ 12.5 mg/min) or diluted in 100 mL of 0.9% NaCl infused over 1 hour per dialysis session ▪ Most patients require a cumulative dose of 1,000 mg elemental iron over 8 dialysis sessions ▪ Pediatric: administer 0.12 mL/kg diluted in 25 mL of 0.9% NaCl infused over 1 hour per dialysis session; maximum dose should not exceed 125 mg per dose	Glass ampules or vials: ▪ 62.5 mg in 5 mL ▪ (12.5 mg/mL) Benzyl alcohol preservative

Iron, Parenteral – Guidelines

- National Kidney Foundation-Kidney Disease Outcomes Quality Initiative, 2006
  - Recommend the use of intravenous (IV) iron formulations as the preferred route of administration in patients with hemodialysis-dependent CKD and as an alternative route in patients with non-dialysis-dependent CKD or peritoneal dialysis-dependent CKD
  - The route of iron administration can be either oral or IV in patients with non-dialysis-dependent CKD or peritoneal dialysis-dependent CKD due to the lack of sufficient evidence supporting 1 route over another
  - The goal of iron therapy is to achieve and maintain a target-range hemoglobin level, avoid storage iron depletion, and prevent iron-deficient erythropoiesis
    - Iron status tests should be performed every 1 to 3 months depending on the patient's hemoglobin level compared to the target range, likelihood of blood loss, and when initiating ESA therapy
  - Parenteral iron replacement may be the primary therapy, or it may be used as an adjuvant therapy for patients receiving erythropoiesis stimulating agents (ESA)
  - Iron can lower the dose requirement for ESA, particularly in patients on dialysis
  - Due to safety concerns associated with erythropoiesis stimulating agents (ESA), there has been an increase in utilization of IV iron formulations in patients with non-dialysis-dependent CKD
  - The selection of parenteral iron products requires the knowledge of dosing, efficacy, safety, and tolerability of available products, while taking into consideration the patient's current CKD stage and the medication administration requirements
  - The 7 intravenous iron products available differ in their indications, dosage, administration, and incidence of adverse effects
    - Newer agents, sodium ferric gluconate complex, iron sucrose, and ferumoxytol, were developed in an effort to improve convenience in administration and reduce the risk of adverse effects like anaphylaxis and hypotension

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Iron, Oral

Hematopoietic Agents: Hematopoietic Mixtures
Hematopoietic Agents: Iron

Iron, Oral - Appendix

LABEL NAME	MANUFACTURER	DRUG TYPE	PROVIDER SYNERGIES BRAND NAME ROUTE
ACTIVE FE TABLET	ALLEGIS PHARMAC	SSB	ACTIVE FE TABLET (ORAL)
CHROMAGEN SOFTGEL	AVION PHARMACEU	SSB	CHROMAGEN CAPSULE OTC (ORAL)
CORVITA 150 TABLET	TRIGEN LABORATO	SSB	CORVITA 150 TABLET (ORAL)
CORVITE 150 TABLET	VERTICAL PHARM	SSB	CORVITE 150 TABLET (ORAL)
CORVITE FE TABLET	VERTICAL PHARM	SSB	CORVITE FE TABLET (ORAL)
FERIVA 21-7 TABLET	AVION PHARMACEU	SSB	FERIVA 21-7 (ORAL)
FERIVA FA CAPSULE	AVION PHARMACEU	SSB	FERIVA FA CAPSULE (ORAL)
FERRALET 90 TABLET	MISSION PHARM.	SSB	FERRALET 90 DUAL-IRON TABLET (ORAL)
FERRAPLUS 90 TABLET	TRIGEN LABORATO	SSB	FERRAPLUS 90 TABLET (ORAL)
FERRIMIN 150 TAB	HILLESTAD PHARM	SSB	FERRIMIN 150 TABLET OTC (ORAL)
FERROUS FUMARATE 324 MG TAB	CYPRESS PHARM.	GEN	FERROUS FUMARATE TABLET OTC (ORAL)
HEMATOGEN FORTE SOFTGEL	NNODUM CORP	GEN	FERROUS FUMARATE/ASCORBIC ACID/B12/FA CAPSULE (ORAL)
TRIGELS-F FORTE SOFTGEL	TRIGEN LABORATO	GEN	FERROUS FUMARATE/ASCORBIC ACID/B12/FA CAPSULE (ORAL)
TL ICON CAPSULE	TRIGEN LABORATO	GEN	FERROUS FUMARATE/ASCORBIC ACID/B12-IF/FA CAPSULE (ORAL)
TRICON CAPSULE	NNODUM CORP	GEN	FERROUS FUMARATE/ASCORBIC ACID/B12-IF/FA CAPSULE (ORAL)
CENTRATEX CAPSULE	CENTURION LABS	GEN	FERROUS FUMARATE/FA/MULTIVITAMIN & MINERALS CAPSULE (ORAL)
PUREVIT DUALFE PLUS CAPSULE	PURETEK CORPORA	GEN	FERROUS FUMARATE/IRON POLYSACCHARIDES/FA/MULTIVITAMIN CAPSULE (ORAL)
SE-TAN PLUS CAPSULE	SETON PHARMACEU	GEN	FERROUS FUMARATE/IRON POLYSACCHARIDES/FA/MULTIVITAMIN CAPSULE (ORAL)
FERATE 27 MG TABLET	MAJOR PHARMACEU	GEN	FERROUS GLUCONATE TABLET OTC (ORAL)
CHILD FERROUS SULFATE 15 MG/ML	HI-TECH/AKORN	GEN	FERROUS SULFATE DROPS OTC (ORAL)
CHILDREN'S IRON 15 MG/ML DROPS	PATRIN PHARMA	GEN	FERROUS SULFATE DROPS OTC (ORAL)
FERROUS SULF 15 MG IRON/ML DRP	SILARX PHARM	GEN	FERROUS SULFATE DROPS OTC (ORAL)
FEROSUL 220 MG/5 ML ELIXIR	MAJOR PHARMACEU	GEN	FERROUS SULFATE SOLUTION OTC (ORAL)
FERROUS SULF 220 MG/5 ML ELIX	SILARX PHARM	GEN	FERROUS SULFATE SOLUTION OTC (ORAL)
FERROUS SULF 220 MG/5 ML LIQ	RUGBY	GEN	FERROUS SULFATE SOLUTION OTC (ORAL)

Iron, Oral - Appendix

HM SLOW RELEASE IRON TABLET	SUNMARK	GEN	FERROUS SULFATE TABLET ER OTC (ORAL)
FEROSUL 325 MG TABLET	MAJOR PHARMACEU	GEN	FERROUS SULFATE TABLET OTC (ORAL)
FERRO-TIME 325 MG TABLET	TIME-CAP LABS	GEN	FERROUS SULFATE TABLET OTC (ORAL)
FERROUS SULFATE 325 MG TABLET	SUN PHARMACEUTICALS	GEN	FERROUS SULFATE TABLET OTC (ORAL)
FERROUSUL 325 MG TABLET	PRIME MARKETING	GEN	FERROUS SULFATE TABLET OTC (ORAL)
IRON 325 MG TABLET	LEADER	GEN	FERROUS SULFATE TABLET OTC (ORAL)
IRON 65 MG TABLET	AMERISOURCEBERG	GEN	FERROUS SULFATE TABLET OTC (ORAL)
IRON 45 MG TABLET	AMERISOURCEBERG	GEN	FERROUS SULFATE, DRIED TABLET ER OTC (ORAL)
FOLITAB 500 CAPLET	RISING PHARM	GEN	FERROUS SULFATE/ASCORBIC ACID/FA TABLET ER OTC (ORAL)
FOLIVANE-F CAPSULE	TRIGEN LABORATO	SSB	FOLIVANE-F CAPSULE (ORAL)
FUSION PLUS CAPSULE	US PHARMACEUTIC	SSB	FUSION PLUS CAPSULE (ORAL)
FUSION SPRINKLES POWDER PACKET	US PHARMACEUTIC	SSB	FUSION SPRINKLES POWDER PACK (ORAL)
HEMATOGEN SOFTGEL	NNODUM CORP	SSB	HEMATOGEN CAPSULE (ORAL)
HEMATOGEN FA SOFTGEL	NNODUM CORP	SSB	HEMATOGEN FA CAPSULE (ORAL)
HEMOCYTE PLUS CAPSULE	US PHARMACEUTIC	SSB	HEMOCYTE PLUS CAPSULE (ORAL)
HEMOCYTE-F TABLET	US PHARMACEUTIC	SSB	HEMOCYTE-F TABLET (ORAL)
INTEGRA F CAPSULE	US PHARMACEUTIC	SSB	INTEGRA F CAPSULE (ORAL)
INTEGRA PLUS CAPSULE	US PHARMACEUTIC	SSB	INTEGRA PLUS CAPSULE (ORAL)
WEE CARE 15 MG/1.25 ML SUSP	CENTURION LABS	GEN	IRON CARBONYL SUSPENSION OTC (ORAL)
IRON CHEWS 15 MG TABLET CHEW	H2 PHARMA LLC	GEN	IRON CARBONYL TABLET CHEWABLE OTC (ORAL)
IRON 100-VITAMIN C TABLET	CYPRESS PHARM.	GEN	IRON CARBONYL/ASCORBIC ACID TABLET OTC (ORAL)
IFEREX 150 CAPSULE	NNODUM CORP	GEN	IRON POLYSACCHARIDES CAPSULE OTC (ORAL)
IFEREX 150 FORTE CAPSULE	NNODUM CORP	GEN	IRON POLYSACCHARIDES/B12/FA CAPSULE (ORAL)
IROSPAN 24/6 TABLET	WOMEN'S CHOICE	SSB	IROSPAN TABLET (ORAL)
NEPHRON FA TABLET	NEPHRO-TECH	SSB	NEPHRON FA TABLET (ORAL)
NIFEREX TABLET	AVION PHARMACEU	SSB	NIFEREX TABLET OTC (ORAL)
NUFERA TABLET	CARWIN ASSOCIAT	SSB	NUFERA TABLET (ORAL)
TANDEM PLUS CAPSULE	US PHARMACEUTIC	SSB	TANDEM PLUS CAPSULE (ORAL)
TARON FORTE CAPSULE	TRIGEN LABORATO	SSB	TARON FORTE CAPSULE (ORAL)
TL-HEM 150 CAPLET	TRIGEN LABORATO	SSB	TL-HEM 150 TABLET ER 24H (ORAL)
VITAFOL CAPLET	EVERETT	SSB	VITAFOL TABLET (ORAL)

Hematopoietic Agents
Iron containing products

- Hematopoietic Agents : Iron
  - Single ingredient oral iron products
  - Single ingredient parenteral iron products
- Hematopoietic Agents : Hematopoietic Mixtures
  - Combination oral iron products

Hematopoietic Agents
Iron containing products

Recommendation:

- All of the iron containing products within each class are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products within that class with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Hematopoietic Agents
Iron containing products

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the iron containing product listed on slide 75 as recommended."

Motion: Flatebo

2nd: Storhaug

Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Pediatric Vitamin Preparations

Vitamins: Pediatric

Pediatric Vitamin Preparations - Appendix

LABEL NAME	MANUFACTURER	DRUG TYPE	PROVIDER SYNERGIES BRAND NAME ROUTE
AQUADEKS PEDIATRIC LIQUID	ACTAVIS U.S. BR	SSB	AQUADEKS DROPS OTC (ORAL)
ANIMAL SHAPES TABLET CHEW	MAJOR PHARMACEU	GEN	CHILD MULTIVITAMINS CHEW OTC (ORAL)
CHILD CHEW VITAMIN TABLET	MAJOR PHARMACEU	GEN	CHILD MULTIVITAMINS CHEW OTC (ORAL)
CHILD'S CHEW MULTIVIT W/IRON	PLUS PHARMA,INC	SSB	CHILDREN'S CHEW MULTIVIT-IRON OTC (ORAL)
CHILDREN'S CHEWABLES	AMERISOURCEBERG	GEN	CHILDREN'S CHEWABLES OTC (ORAL)
CHILD'S CHEWABLE MULTIVIT TAB	PLUS PHARMA,INC	GEN	CHILDREN'S CHEWABLES OTC (ORAL)
ZOO FRIENDS ORIGINAL TAB CHEW	LEADER	GEN	CHILDREN'S CHEWABLES OTC (ORAL)
CHILD CHEW + IRON TAB CHEW	MAJOR PHARMACEU	GEN	CHILDREN'S VITAMINS WITH IRON CHEW OTC (ORAL)
VITALETS TABLET CHEWABLE	FREEDA VITAMINS	GEN	CHILDREN'S VITAMINS WITH IRON CHEW OTC (ORAL)
ESCAVITE TABLET CHEWABLE	G.M. PHARM	SSB	ESCAVITE (ORAL)
ESCAVITE D TABLET CHEWABLE	G.M. PHARM	SSB	ESCAVITE D CHEW TAB (ORAL)
ESCAVITE LQ DROPS	G.M. PHARM	SSB	ESCAVITE LQ (ORAL)
FLORIVA 0.25 MG CHEW TABLET	BONGEO PHARMACE	SSB	FLORIVA CHEW (ORAL)
FLORIVA 0.5 MG CHEWABLE TABLET	BONGEO PHARMACE	SSB	FLORIVA CHEW (ORAL)
FLORIVA 1 MG CHEWABLE TABLET	BONGEO PHARMACE	SSB	FLORIVA CHEW (ORAL)
FLORIVA PLUS 0.25 MG/ML DROP	BONGEO PHARMACE	SSB	FLORIVA PLUS DROPS OTC (ORAL)
TRI-VIT-FLUOR 0.25 MG/ML DROP	SANCILIO & COMP	GEN	FLUORIDE/VITAMINS A,C,AND D DROPS (ORAL)
VIT A,C,D-FLUORIDE 0.25 MG/ML	H2 PHARMA LLC	GEN	FLUORIDE/VITAMINS A,C,AND D DROPS (ORAL)
MULTIVIT-FLUOR 0.25 MG/ML DROP	METHOD PHARMACE	GEN	MULTIVITAMINS WITH FLUORIDE DROPS (ORAL)
MULTIVIT-FLUOR 0.5 MG/ML DROP	METHOD PHARMACE	GEN	MULTIVITAMINS WITH FLUORIDE DROPS (ORAL)
MULTIVIT-FLUOR 0.25 MG/ML DROP	SANCILIO & COMP	GEN	MULTIVITAMINS WITH FLUORIDE DROPS OTC (ORAL)
MULTIVIT-FLUOR 0.5 MG/ML DROP	SANCILIO & COMP	GEN	MULTIVITAMINS WITH FLUORIDE DROPS OTC (ORAL)
ABDEK MULTIVITAMIN CHEW TAB	H2 PHARMA LLC	GEN	MULTIVITAMINS-A,B,D,E,K,ZN DROPS OTC (ORAL)
ABDEK MULTIVITAMIN DROP	H2 PHARMA LLC	GEN	MULTIVITAMINS-A,B,D,E,K,ZN DROPS OTC (ORAL)
MULTIVIT-FLUOR-IRON 0.25 MG/ML	METHOD PHARMACE	GEN	MULTIVITS WITH IRON & FLUORIDE DROPS (ORAL)
MULTIVIT-IRON-FLUOR 0.25 MG/ML	H2 PHARMA LLC	GEN	MULTIVITS WITH IRON & FLUORIDE DROPS (ORAL)
MULTIVIT-FLUOR-IRON 0.25 MG/ML	SANCILIO & COMP	GEN	MULTIVITS WITH IRON & FLUORIDE DROPS OTC (ORAL)
MVC-FLUORIDE 0.25 MG TAB CHEW	SANCILIO & COMP	SSB	MVC-FLUORIDE CHEW (ORAL)
MVC-FLUORIDE 0.5 MG TAB CHEW	SANCILIO & COMP	SSB	MVC-FLUORIDE CHEW (ORAL)
MVC-FLUORIDE 1 MG TAB CHEW	SANCILIO & COMP	SSB	MVC-FLUORIDE CHEW (ORAL)
TRI-VIT-FLUOR 0.5 MG/ML DROP	SANCILIO & COMP	GEN	PED MVIT A,C,D3 NO.21/FLUORIDE DROPS (ORAL)
MULTIVIT-FLUOR 0.25 MG TAB CHW	H2 PHARMA LLC	GEN	PEDI MVI NO.16 WITH FLUORIDE TAB CHEW (ORAL)
MULTIVIT-FLUOR 0.5 MG TAB CHEW	H2 PHARMA LLC	GEN	PEDI MVI NO.16 WITH FLUORIDE TAB CHEW (ORAL)
MULTIVIT-FLUORIDE 1 MG TAB CHW	H2 PHARMA LLC	GEN	PEDI MVI NO.16 WITH FLUORIDE TAB CHEW (ORAL)
MULTIVIT-FLUOR 0.25 MG TAB CHW	METHOD PHARMACE	GEN	PEDI MVI NO.17 WITH FLUORIDE CHEW (ORAL)
MULTIVIT-FLUOR 0.5 MG TAB CHEW	METHOD PHARMACE	GEN	PEDI MVI NO.17 WITH FLUORIDE CHEW (ORAL)
MULTIVIT-FLUOR 0.5 MG TAB CHW	BOCA PHARMACAL	GEN	PEDI MVI NO.17 WITH FLUORIDE CHEW (ORAL)
MULTIVIT-FLUORIDE 1 MG TAB CHW	METHOD PHARMACE	GEN	PEDI MVI NO.17 WITH FLUORIDE CHEW (ORAL)

Pediatric Vitamin Preparations - Appendix

POLY-VI-FLOR 0.25 MG TAB CHEW	ZYLERA	SSB	POLY-VI-FLOR CHEW (ORAL)
POLY-VI-FLOR 0.5 MG TAB CHEW	ZYLERA	SSB	POLY-VI-FLOR CHEW (ORAL)
POLY-VI-FLOR 1 MG TAB CHEW	ZYLERA	SSB	POLY-VI-FLOR CHEW (ORAL)
POLY-VI-FLOR 0.25 MG DROPS	ZYLERA	SSB	POLY-VI-FLOR DROPS (ORAL)
POLY-VI-FLOR WITH IRON 0.5 MG	ZYLERA	SSB	POLY-VI-FLOR WITH IRON CHEW (ORAL)
POLY-VI-FLOR WITH IRON 0.25 MG	ZYLERA	SSB	POLY-VI-FLOR WITH IRON DROPS (ORAL)
POLY-VI-SOL DROPS	MJ NUTRITIONAL	SSB	POLY-VI-SOL DROPS OTC (ORAL)
POLY-VI-SOL WITH IRON DROPS	MJ NUTRITIONAL	SSB	POLY-VI-SOL WITH IRON DROPS OTC (ORAL)
QUFLORA PED 0.25 MG CHEW TAB	CARWIN ASSOCIAT	SSB	QUFLORA (ORAL)
QUFLORA PED 0.25 MG/ML DROP	CARWIN ASSOCIAT	SSB	QUFLORA (ORAL)
QUFLORA PED 0.5 MG CHEW TAB	CARWIN ASSOCIAT	SSB	QUFLORA (ORAL)
QUFLORA PED 0.5 MG/ML DROP	CARWIN ASSOCIAT	SSB	QUFLORA (ORAL)
QUFLORA PED 1 MG CHEW TAB	CARWIN ASSOCIAT	SSB	QUFLORA (ORAL)
QUFLORA FE 0.25 MG CHEW TABLET	CARWIN ASSOCIAT	SSB	QUFLORA FE (ORAL)
QUFLORA FE PED 0.25 MG/ML DROP	CARWIN ASSOCIAT	SSB	QUFLORA FE (ORAL)
QUFLORA 0.125 MG GUMMIES	CARWIN ASSOCIAT	SSB	QUFLORA OTC (ORAL)
TRI-VI-FLOR 0.25 MG DROPS	ZYLERA	SSB	TRI-VI-FLORO DROPS (ORAL)
TRI-VI-FLOR 0.5 MG DROPS	ZYLERA	SSB	TRI-VI-FLORO DROPS (ORAL)
TRI-VI-SOL DROPS	MJ NUTRITIONAL	SSB	TRI-VI-SOL DROPS OTC (ORAL)
TRI-VITE-FLUORIDE 0.25 MG/ML	METHOD PHARMACE	GEN	TRI-VITAMIN WITH FLUORIDE (ORAL)
TRI-VITE-FLUORIDE 0.5 MG/ML	METHOD PHARMACE	GEN	TRI-VITAMIN WITH FLUORIDE (ORAL)
VITALETS TABLET CHEWABLE	FREEDA VITAMINS	SSB	VITALETS CHEW OTC (ORAL)

Vitamins : Pediatric

- **Recommendation:**
  - All pediatric vitamin products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
  - All non-preferred products require a trial of two preferred products with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Vitamins : Pediatric

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the Vitamins : Pediatric drug class listed on slide 80 as recommended.”

Motion: Flatebo

2nd: Chew

Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Analgesics, Narcotic Injectable

Analgesics- Opioid: Injectables

Analgesics, Narcotic Injectable - Appendix

LABEL NAME	MANUFACTURER	DRUG TYPE	PROVIDER SYNERGIES BRAND NAME ROUTE
ASTRAMORPH-PF 1 MG/2 ML AMPULE	APP PHARMACEUTI	GEN	ASTRAMORPH-PF AMPUL (INJECTION)
ASTRAMORPH-PF 1 MG/ML AMPUL	APP PHARMACEUTI	GEN	ASTRAMORPH-PF AMPUL (INJECTION)
BUPRENEX 0.3 MG/ML AMPUL	INDIVIOR INC.	SSB	BUPRENEX AMPUL (INJECTION)
BUPRENORPHINE 0.3 MG/ML SYRING	HOSPIRA	GEN	BUPRENORPHINE SYRINGE (INJECTION)
BUPRENORPHINE 0.3 MG/ML VIAL	PAR PHARM.	GEN	BUPRENORPHINE VIAL (INJECTION)
BUTORPHANOL 1 MG/ML VIAL	HOSPIRA	GEN	BUTORPHANOL TARTRATE VIAL (INJECTION)
BUTORPHANOL 2 MG/ML VIAL	HOSPIRA	GEN	BUTORPHANOL TARTRATE VIAL (INJECTION)
DEMEROL 100 MG/2 ML AMPUL	HOSPIRA	SSB	DEMEROL AMPUL (INJECTION)
DEMEROL 100 MG/ML AMPUL	HOSPIRA	SSB	DEMEROL AMPUL (INJECTION)
DEMEROL 25 MG/0.5 ML AMPUL	HOSPIRA	SSB	DEMEROL AMPUL (INJECTION)
DEMEROL 50 MG/ML AMPUL	HOSPIRA	SSB	DEMEROL AMPUL (INJECTION)
DEMEROL 75 MG/1.5 ML AMPUL	HOSPIRA	SSB	DEMEROL AMPUL (INJECTION)
DEMEROL 100 MG/ML CARPUJECT	HOSPIRA	SSB	DEMEROL SYRINGE (INJECTION)
DEMEROL 25 MG/ML CARPUJECT	HOSPIRA	SSB	DEMEROL SYRINGE (INJECTION)
DEMEROL 50 MG/ML CARPUJECT	HOSPIRA	SSB	DEMEROL SYRINGE (INJECTION)
DEMEROL 75 MG/ML SYRINGE	HOSPIRA	SSB	DEMEROL SYRINGE (INJECTION)
DEMEROL 100 MG/ML VIAL	HOSPIRA	SSB	DEMEROL VIAL (INJECTION)
DEMEROL 50 MG/ML VIAL	HOSPIRA	SSB	DEMEROL VIAL (INJECTION)
DILAUDID 0.5 MG/0.5 ML SYRINGE	FRESENIUS KABI	SSB	DILAUDID SYRINGE (INJECTION)
DILAUDID 1 MG/ML SYRINGE	FRESENIUS KABI	SSB	DILAUDID SYRINGE (INJECTION)
DILAUDID 2 MG/ML SYRINGE	FRESENIUS KABI	SSB	DILAUDID SYRINGE (INJECTION)
DILAUDID 4 MG/ML SYRINGE	FRESENIUS KABI	SSB	DILAUDID SYRINGE (INJECTION)
FENTANYL 100 MCG/2 ML SYRINGE	HOSPIRA	GEN	FENTANYL CITRATE/PF SYRINGE (INTRAVENOUS)
HYDROMORPHONE HCL 1 MG/ML AMP	HOSPIRA	GEN	HYDROMORPHONE PF AMPUL (INJECTION)
HYDROMORPHONE HCL 2 MG/ML AMP	HOSPIRA	GEN	HYDROMORPHONE PF AMPUL (INJECTION)
HYDROMORPHONE HCL 4 MG/ML AMP	HOSPIRA	GEN	HYDROMORPHONE PF AMPUL (INJECTION)

Analgesics, Narcotic Injectable - Appendix

HYDROMORPHONE 1 MG/ML VIAL	FRESENIUS KABI	GEN	HYDROMORPHONE PF VIAL (AG) (INJECTION)
HYDROMORPHONE 10 MG/ML VIAL	FRESENIUS KABI	GEN	HYDROMORPHONE PF VIAL (AG) (INJECTION)
HYDROMORPHONE 4 MG/ML VIAL	FRESENIUS KABI	GEN	HYDROMORPHONE PF VIAL (AG) (INJECTION)
HYDROMORPHONE 50 MG/5 ML VIAL	FRESENIUS KABI	GEN	HYDROMORPHONE PF VIAL (AG) (INJECTION)
HYDROMORPHONE 500 MG/50 ML VL	FRESENIUS KABI	GEN	HYDROMORPHONE PF VIAL (AG) (INJECTION)
HYDROMORPHONE 10 MG/ML VIAL	TEVA PARENTERAL	GEN	HYDROMORPHONE PF VIAL (INJECTION)
HYDROMORPHONE 50 MG/5 ML VIAL	TEVA PARENTERAL	GEN	HYDROMORPHONE PF VIAL (INJECTION)
HYDROMORPHONE 500 MG/50 ML VIA	HOSPIRA	GEN	HYDROMORPHONE PF VIAL (INJECTION)
HYDROMORPHONE HCL 10 MG/ML VL	AKORN INC.	GEN	HYDROMORPHONE PF VIAL (INJECTION)
HYDROMORPHONE 0.5 MG/0.5 ML	HOSPIRA	GEN	HYDROMORPHONE SYRINGE (INJECTION)
HYDROMORPHONE 1 MG/ML CARPUJCT	HOSPIRA	GEN	HYDROMORPHONE SYRINGE (INJECTION)
HYDROMORPHONE 1 MG/ML SYRINGE	HOSPIRA	GEN	HYDROMORPHONE SYRINGE (INJECTION)
HYDROMORPHONE 2 MG/ML CARPUJCT	HOSPIRA	GEN	HYDROMORPHONE SYRINGE (INJECTION)
HYDROMORPHONE 2 MG/ML ISECURE	HOSPIRA	GEN	HYDROMORPHONE SYRINGE (INJECTION)
HYDROMORPHONE 4 MG/ML CARPUJCT	HOSPIRA	GEN	HYDROMORPHONE SYRINGE (INJECTION)
HYDROMORPHONE 2 MG/ML VIAL	FRESENIUS KABI	GEN	HYDROMORPHONE VIAL (INJECTION)
HYDROMORPHONE HCL 10 MG/ML AMP	AKORN INC.	GEN	HYDROMORPHONE/PF AMPUL (INJECTION)
INFUMORPH 200 MG/20 ML AMPUL	WEST-WARD,INC.	SSB	INFUMORPH AMPUL (INJECTION)
INFUMORPH 500 MG/20 ML AMPUL	WEST-WARD,INC.	SSB	INFUMORPH AMPUL (INJECTION)
MEPERIDINE 10 MG/ML CARTRDGE	HOSPIRA	GEN	MEPERIDINE CARTRIDGE (INJECTION)
MEPERIDINE 100 MG/ML VIAL	WEST-WARD,INC.	GEN	MEPERIDINE PF VIAL (INJECTION)
MEPERIDINE 25 MG/ML VIAL	WEST-WARD,INC.	GEN	MEPERIDINE PF VIAL (INJECTION)
MEPERIDINE 50 MG/ML VIAL	WEST-WARD,INC.	GEN	MEPERIDINE PF VIAL (INJECTION)
METHADONE HCL 10 MG/ML VIAL	MYLAN INSTITUTI	GEN	METHADONE VIAL (INJECTION)
METHADONE HCL 200 MG/20 ML VL	AKORN INC.	GEN	METHADONE VIAL (INJECTION)
MITIGO 200 MG/20 ML VIAL	PIRAMAL CRITICA	SSB	MITIGO (INJECTION)
MITIGO 500 MG/20 ML VIAL	PIRAMAL CRITICA	SSB	MITIGO (INJECTION)
MORPHINE 10 MG/ML CARPUJECT	HOSPIRA	GEN	MORPHINE CARTRIDGE (INTRAVENOUS)
MORPHINE 2 MG/ML CARPUJECT	HOSPIRA	GEN	MORPHINE CARTRIDGE (INTRAVENOUS)
MORPHINE 4 MG/ML CARPUJECT	HOSPIRA	GEN	MORPHINE CARTRIDGE (INTRAVENOUS)
MORPHINE 8 MG/ML CARPUJECT	HOSPIRA	GEN	MORPHINE CARTRIDGE (INTRAVENOUS)
MORPHINE 30 MG/30 ML SYRINGE	INTERNATIONAL M	GEN	MORPHINE PCA SYRINGE (INTRAVENOUS)
MORPHINE 5 MG/ML VIAL	HOSPIRA	GEN	MORPHINE PF PCA VIAL (INTRAVENOUS)
MORPHINE SULFATE 1 MG/ML VIAL	HOSPIRA	GEN	MORPHINE PF PCA VIAL (INTRAVENOUS)
MORPHINE 0.5 MG/ML VIAL	HOSPIRA	GEN	MORPHINE PF VIAL (INJECTION)
MORPHINE 1 MG/ML VIAL P-F	HOSPIRA	GEN	MORPHINE PF VIAL (INJECTION)
MORPHINE 10 MG/ML SYRINGE	BD RX INC.	GEN	MORPHINE SYRINGE (INJECTION)
MORPHINE 2 MG/ML SYRINGE	BD RX INC.	GEN	MORPHINE SYRINGE (INJECTION)

Analgesics, Narcotic Injectable - Appendix

LABEL NAME	MANUFACTURER	DRUG TYPE	PROVIDER SYNERGIES BRAND NAME ROUTE
MORPHINE 4 MG/ML SYRINGE	BD RX INC.	GEN	MORPHINE SYRINGE (INJECTION)
MORPHINE 5 MG/ML SYRINGE	BD RX INC.	GEN	MORPHINE SYRINGE (INJECTION)
MORPHINE 8 MG/ML SYRINGE	BD RX INC.	GEN	MORPHINE SYRINGE (INJECTION)
MORPHINE 10 MG/ML ISECURE SYRG	HOSPIRA	GEN	MORPHINE SYRINGE (INTRAVENOUS)
MORPHINE 2 MG/ML ISECURE SYR	HOSPIRA	GEN	MORPHINE SYRINGE (INTRAVENOUS)
MORPHINE 4 MG/ML ISECURE SYR	HOSPIRA	GEN	MORPHINE SYRINGE (INTRAVENOUS)
MORPHINE 8 MG/ML ISECURE SYRNG	HOSPIRA	GEN	MORPHINE SYRINGE (INTRAVENOUS)
MORPHINE SULFATE 10 MG/ML VIAL	FRESENIUS KABI	GEN	MORPHINE VIAL (AG) (INJECTION)
MORPHINE SULFATE 2 MG/ML VIAL	FRESENIUS KABI	GEN	MORPHINE VIAL (AG) (INJECTION)
MORPHINE SULFATE 4 MG/ML VIAL	FRESENIUS KABI	GEN	MORPHINE VIAL (AG) (INJECTION)
MORPHINE SULFATE 5 MG/ML VIAL	FRESENIUS KABI	GEN	MORPHINE VIAL (AG) (INJECTION)
MORPHINE SULFATE 8 MG/ML VIAL	FRESENIUS KABI	GEN	MORPHINE VIAL (AG) (INJECTION)
MORPHINE SULFATE 25 MG/ML VIAL	HOSPIRA	GEN	MORPHINE VIAL (INTRAVENOUS)
MORPHINE SULFATE 4 MG/ML VIAL	WEST-WARD,INC.	GEN	MORPHINE VIAL (INTRAVENOUS)
MORPHINE SULFATE 50 MG/ML VIAL	HOSPIRA	GEN	MORPHINE VIAL (INTRAVENOUS)
MORPHINE SULFATE 8 MG/ML VIAL	WEST-WARD,INC.	GEN	MORPHINE VIAL (INTRAVENOUS)
MORPHINE SULFATE 25 MG/ML VL	HOSPIRA	GEN	MORPHINE VIAL PORT (INTRAVENOUS)
NALBUPHINE 10 MG/ML AMPUL	HOSPIRA	GEN	NALBUPHINE AMPUL (INJECTION)
NALBUPHINE 20 MG/ML AMPUL	HOSPIRA	GEN	NALBUPHINE AMPUL (INJECTION)
NALBUPHINE 100 MG/10 ML VIAL	HOSPIRA	GEN	NALBUPHINE VIAL (INJECTION)
NALBUPHINE 200 MG/10 ML VIAL	HOSPIRA	GEN	NALBUPHINE VIAL (INJECTION)

Analgesics - Opioid : Injectables

- **Current Limitations:**
  - Therapeutic class will not be included in the Apple Health PDL at this time
  - Varies based on plan
- **Recommendations:**
  - Continue current limitations

Analgesics - Opioid : Injectables

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the Analgesics - Opioid : Injectables drug class listed on slide 86 as recommended."

Motion: Lee

2nd: Park