



# Apple Health Preferred Drug List Policies

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# PCSK-9 Inhibitors

Praluent, Repatha

Heterozygous Familial Hypercholesterolemia ( $\geq 18$  years)  
defined by **ONE** of the following:

- clinical diagnosis using diagnostic tools such as US MedPed, Simon Broome Register Group, or Dutch Lipid Panel
- age  $\geq 20$  and LDL  $\geq 190$ mg/dL on maximally tolerated statin therapy prior to adding a PCSK9 Inhibitor
- age  $< 20$  and LDL  $\geq 160$ mg/dL on maximally tolerated statin therapy prior to adding a PCSK9 Inhibitor
- genetic typing confirming presence of familial hypercholesterolemia genes

# PCSK-9 Inhibitors

Praluent, Repatha

Clinical Atherosclerotic Cardiovascular Disease ( $\geq 18$  years) including at least **one** of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

# PCSK-9 Inhibitors

## Repatha only

Homozygous familial hypercholesterolemia ( $\geq 13$  years) defined by **one** of the following:

- history of untreated LDL  $\geq 500$ mg/dL with either a xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents;
- genetic typing confirming presence of Familial Hypercholesterolemia genes

Risk reduction of myocardial infarction (MI), stroke, and coronary revascularization in adults with established cardiovascular disease (CVD)

# PCSK-9 Inhibitors

## Praluent, Repatha

Concomitant therapy with the highest-tolerated statin regimen for at least 6 consecutive weeks and LDL has not achieved at least 50% reduction from baseline or remains greater than or equal to 100 mg /dl

- Highest-tolerated dose is defined as **ONE** of the following:
  - FDA labeled maximum dose for high-intensity statin therapy (e.g. atorvastatin 40 to 80mg and rosuvastatin 20 to 40mg)
  - Treatment with maximally tolerated statin therapy has been ineffective, contraindicated, or not tolerated.
    - A statin is considered ineffective if patients are not able to tolerate high-intensity or have not had an LDL-C reduction of at least 50% while on a maximally tolerated dose of statin **with or with out** concurrent trial of ezetimibe for at least 6 weeks.
    - Statin intolerance is defined as the inability to tolerate (reference policy from 2015 for intolerance definition. Primary care physician can prescribe.) at least two different statin medications at the lowest FDA-approved starting dose when other potential causes of muscle symptoms have been maximally managed or ruled out

# PCSK9

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the PCSK9 drug class as listed on slides #2-5.”

Motion: Figueroa

2<sup>nd</sup>: Storhaug

# Apolipoprotein B Synthesis Inhibitors (Juxtapid or Kynamro)

- Homozygous familial hypercholesterolemia (HoFH) confirmed by **one** of the following:
  - Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus.
  - Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality
  - An untreated low density lipoprotein (LDL) cholesterol > 500mg/dL and TG < 300 mg/dL and both parents with documented untreated TC > 250 mg/dL with either:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of heterozygous familial hypercholesterolemia in both parents
- Greater than or equal to ( $\geq$ ) 18 years of age
- Prescribed by or in consultation with a provider specializing in lipid management (e.g. cardiologist, lipid specialist, or endocrinologist)

# Apolipoprotein B Synthesis Inhibitors

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the Apolipoprotein B Synthesis Inhibitors as listed on slide #7.”

Motion: Figueroa

2<sup>nd</sup>: Flatebo



# Atopic Dermatitis Agents

## (Elidel or Protopic)

- Diagnosis of atopic dermatitis (eczema)
- History of failure (failure to achieve and maintain remission of disease), intolerance, or contraindication to, or clinical inappropriateness of, 2 topical corticosteroid for daily treatment of minimum 14-days
- Greater than or equal to ( $\geq$ ) 2 years of age
- Dose limits (exception for prescriptions written by dermatologist):
  - Elidel<sup>®</sup> and tacrolimus 0.03%: greater than or equal to ( $\geq$ ) 2 years of age
  - Tacrolimus 0.1%: Greater than or equal to ( $\geq$ ) 16 years of age

# Atopic Dermatitis Agents (Eucrisa)

- Diagnosis of atopic dermatitis (eczema)
- History of failure (unable to achieve or maintain remission of low or mild disease), intolerance, or contraindication to, or clinical inappropriateness of, daily use of both of the following:
  - Two topical corticosteroids for at least 14-days
  - topical calcineurin inhibitors for at least 28-days
- Greater than or equal to ( $\geq$ ) 2 years of age

# Atopic Dermatitis Agents (Dupixent)

- Diagnosis of severe chronic atopic dermatitis involving at least 10% of body surface area (BSA)
- Clinical documentation of functional impairment due to atopic dermatitis
- History of failure (unable to achieve or maintain low or mild disease), intolerance, or contraindication to, or clinical inappropriateness of, the following therapies:
  - Topical corticosteroids for at least 14-days of daily treatment
  - Topical calcineurin inhibitors for at least 28-days of daily treatment
  - Systemic treatment with immunosuppressant agents or Phototherapy
- Greater than or equal to ( $\geq$ ) 18 years of age
- Prescribed by or in consultation with a provider in dermatology.

# Atopic Dermatitis Agents

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the Atopic Dermatitis Agents as listed on slides #9-11.”

Motion: Figueroa

2<sup>nd</sup>: Flatebo

# Bone Density Regulators (Tymlos)

- Diagnosis of osteoporosis in postmenopausal women with a high risk for fracture defined by **ONE** of the following criterion:
  - Bone mineral density (BMD) that is 2.5 or more standard deviations below that of a “young normal” adult (T score at or below -2.5 from the femoral neck, total hip, or lumbar spine).
  - The patient has osteopenia (T score between -1 and -2.5 from the femoral neck, total hip, or lumbar spine) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent).
- History of a contraindication, or intolerance to two oral bisphosphonates, and one selective estrogen receptor modulator; or
- A history or failure of a two year trial of one oral bisphosphonate **or** one selective estrogen receptor modulator (SERM) (e.g. raloxifene)
- Total combined duration of use not to exceed 2 years (e.g. tymlos, forteo)



# Bone Density Regulators (Prolia)

- **ONE** of the following:
  - Patient is a man or postmenopausal woman and is diagnosed with osteoporosis, defined as a T-score  $\leq -2.5$  at the femoral neck, total hip, or lumbar spine
  - Patient is a man who is receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer
  - Patient is a woman who is receiving adjuvant aromatase inhibitor (AI) therapy for breast cancer
- History of failure, contraindication, or intolerance to at least one (1) oral bisphosphonate and IV zoledronic acid
- **NONE** of the following:
  - Prescribed for the prevention of osteoporosis or for the prevention or treatment of glucocorticoid-induced osteoporosis
  - Uncorrected pre-existing hypocalcemia
  - Currently pregnant
  - Currently receiving XGEVA (denosumab)



# Bone Density Regulators (Forteo)

- Diagnosis of osteoporosis with high risk for fractures defined by **ONE** of the following:
  - Treatment of postmenopausal women with osteoporosis at high risk for fracture
  - Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
  - Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- Diagnosis of osteoporosis with high risk for fracture as defined by either of the following:
  - Bone mineral density (BMD) that is 2.5 or more standard deviations below that of a “young normal” adult (T score at or below -2.5 from the femoral neck, total hip, or lumbar spine).
  - The patient has osteopenia (T score between -1 and -2.5 from the femoral neck, total hip, or lumbar spine) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent).



# Bone Density Regulators (Forteo)

- History of a contraindication, or intolerance to two oral bisphosphonates, and one selective estrogen receptor modulator; or
- A history or failure of a two year trial of one oral bisphosphonate **or** one selective estrogen receptor modulator (SERM) (e.g. raloxifene)
- Greater than or equal to ( $\geq$ ) 18 years of age with closed epiphyses
- Total duration of use not to exceed 2 years





# Bone Density Regulators

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the Bone Density Regulators as listed on slides #13-16.”

Motion: Chew

2<sup>nd</sup>: Lee



# Amylin Analogs (Symlin, SymlinPen)

- Diagnosis of Type 1 or Type 2 diabetes
- Failed to achieve desired glycemic control despite optimal insulin therapy
- Currently receiving optimal mealtime insulin or continuous insulin infusion (insulin pump)
- **NONE** of the following:
  - Diagnosis of gastroparesis or requiring medication to stimulate gastrointestinal motility (i.e. metoclopramide or erythromycin)
  - Hypoglycemia unawareness (e.g., inability to detect and act upon the signs or symptoms of hypoglycemia)
  - Poor compliance with current insulin regimen
  - Poor compliance with self-blood glucose monitoring
  - HbA1C (hemoglobin A1c) level greater than (>) 9% within the last 3 months
  - Recurrent severe hypoglycemia that required assistance during the past 6 months



# Amylin Analogs

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the Amylin Analogs as listed on slide #18.”

Motion: Figueroa

2<sup>nd</sup>: Chew

# Afrezza

## Inhaled Insulin

- **ONE** of the following:
  - Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump
  - Diagnosis of type 2 diabetes mellitus
- History of failure (ineffective in reducing A1C to goal of 9% or less after 90 days), contraindication or intolerance to injectable insulin regimen containing a prandial insulin.
- Documentation of inability to self-Inject medication
- FEV1 within the last 60 days in greater than or equal to ( $\geq$ ) 70% of predicted as determined by prescriber
- **NONE** of the following:
  - History of chronic lung disease (e.g. asthma or COPD)
  - Current smoker/vaper



# Afrezza

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for Afrezza as listed on slide #20.”

Motion: Chew

2<sup>nd</sup>: Park

# Ampyra

(dalfampridine)

- Diagnosis of multiple sclerosis (MS)
- Concurrent use of, documented intolerance, or contraindication of disease modifying agent for MS
- Greater than or equal to ( $\geq$ ) 18 years of age
- NONE of the following:
  - History of seizures
  - Moderate to severe renal insufficiency ( $\text{CrCl} \leq 50 \text{ mL/min}$ )
  - Non-ambulatory
- Prescribed by or in consultation with a neurology specialist
- Maximum 20mg per day (10mg every 12 hours)



# Ampyra

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for Ampyra as listed on slide #22.”

Motion: Flatebo

2<sup>nd</sup>: Schwilke



# Makena

(hydroxyprogesterone caproate)

- Diagnosis of singleton pregnancy
- Prior history of singleton preterm delivery before 37 weeks of gestation
- To be initiated on or after 16 weeks 0 days and continued until 36 weeks 6 days of gestation or delivery, whichever comes first
- Maximum dose:
  - Vial; 250mg IM once weekly
  - Auto-injector; 275mg SQ once weekly
- Greater than or equal to ( $\geq$ ) 16 years of age



# Makena

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for Makena as listed on slide #24.”

Motion: Figueroa

2<sup>nd</sup>: Flatebo

# Midazolam

## (Seizure Rescue Agent)

- Diagnosis of seizure or epilepsy
- Administered intranasally as a rescue agent for prolonged seizures lasting longer than 3 minutes
- Prescribed by or in consultation with a neurology/epileptology specialist
- Documentation that patient and/or caregiver has been provided proper training on administration and follow-up after administration of midazolam
- Documentation that patient and/or caregiver has been counselled on the risks of use with midazolam
- Maximum 10mg per dose



# Midazolam

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for Midazolam as listed on slide #26.”

Motion: Chew

2<sup>nd</sup>: Brown



# Dronabinol

## (Marinol, Syndros)

- Anorexia associated with weight loss in adults with AIDS
  - ONE of the following:
    - Involuntary weight loss in adults of greater than 10% of pre-illness baseline body weight
    - BMI less than 20kg/m<sup>2</sup> in the absence of concurrent illness or medical condition other than AIDS that may cause weight loss
  - History of failure, contraindication or intolerance to conventional therapies (e.g. megestrol (Megace®))
  - Dose limit
    - Marinol: 20mg per day
    - Syndros: 8.4mg twice daily
- Prescribed by or in consultation with an HIV specialist



# Dronabinol

(Marinol, Syndros)

- Nausea and vomiting associated with chemotherapy in adults
  - Current diagnosis of cancer or history of cancer diagnosis in last year
  - Currently receiving chemotherapy or history of chemotherapy in the last year
  - History of failure, contraindication or intolerance to conventional therapy (e.g. dexamethasone, ondansetron, aprepitant)
- Dose limit
  - Marinol: 15mg/m<sup>2</sup> per dose for 4 to 6 doses per day
  - Syndros: 12.6mg/m<sup>2</sup> per dose for 4 to 6 doses per day
- Prescribed by or in consultation with an oncology specialist



# Dronabinol

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for Dronabinol as listed on slides #28-29.”

Motion: Flatebo

2<sup>nd</sup>: Lee

