AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: cinacalcet (Sensipar®)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Quantity Limits:

- **cinacalcet 30 mg tablet: 2 tablets per day**
- **cinacalcet 60 mg tablet: 2 tablets per day**
- **cinacalcet 90 mg tablet: 4 tablets per day**

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

Please select one of the following diagnoses:

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❑ Diagnosis: Secondary Hyperthyroidism

- ❑ Must be prescribed by or in consultation with a nephrologist or endocrinologist
- ❑ Member is at least 18 years of age
- ❑ Member has a diagnosis of chronic kidney disease (CKD)
- ❑ Member is currently undergoing dialysis
- ❑ Baseline (pre-treatment) intact parathyroid hormone (iPTH) >300 pg/mL OR bio-intact parathyroid hormone (biPTH) >160 pg/ml **(labs must be submitted with request)**
- ❑ Baseline serum calcium (Ca) >8.4 mg/dL (corrected for albumin) **(labs must be submitted with request)**
- ❑ Member has a documented failure, contraindication, or ineffective response at maximumally tolerated doses to a minimum (3) month trial with a vitamin D agent e.g., calcitriol, doxercalciferol, paricalcitol **(verified by pharmacy paid claims)**
- ❑ Member has a documented failure, contraindication, or ineffective response at maximumally tolerated doses to a minimum (3) month trial with a phosphate binder e.g., calcium carbonate, calcium acetate, sevelamer hydrochloride, sevelamer carbonate, lanthanum carbonate **(verified by pharmacy paid claims)**

❑ Diagnosis: Parathyroid Carcinoma

- ❑ Must be prescribed by or in consultation with an oncologist, nephrologist or endocrinologist
- ❑ Member is at least 18 years of age
- ❑ Member has a diagnosis of parathyroid carcinoma
- ❑ Confirmation the patient has hypercalcemia as defined by baseline serum calcium (Ca) >10 mg/dL (corrected for albumin) **(labs must be submitted with request)**

❑ Diagnosis: Primary Hyperparathyroidism

- ❑ Must be prescribed by or in consultation with a nephrologist or endocrinologist
- ❑ Member is at least 18 years of age
- ❑ Confirmation the patient has severe hypercalcemia as defined by baseline (pre-treatment) serum calcium (Ca) >12 mg/dL (corrected for albumin) **(labs must be submitted with request)**
- ❑ Confirmation that parathyroidectomy is indicated but patient is unable to undergo surgery **(labs must be submitted with request)**

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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Please select one of the following diagnoses:

❑ Diagnosis: Secondary Hyperthyroidism

- ❑ Absence of unacceptable toxicity from the drug (e.g. hypocalcemia, upper gastrointestinal bleeding, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease)
- ❑ Adequate documentation of disease response as indicated by improvement of intact parathyroid hormone (iPTH) levels from pretreatment baseline has been submitted
- ❑ Current intact parathyroid hormone (iPTH) >150 pg/ml **(labs must be submitted with request)**
- ❑ Current serum calcium (Ca) >7.5 mg/dL AND the patient does not have symptoms of hypocalcemia **(labs must be submitted with request)**

❑ Diagnosis: Parathyroid Carcinoma

- ❑ Absence of unacceptable toxicity from the drug (e.g. hypocalcemia, upper gastrointestinal bleeding, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease)
- ❑ Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from pretreatment baseline has been submitted
- ❑ Current serum calcium (Ca) >8.4 mg/dL **(labs must be submitted with request)**

❑ Diagnosis: Primary Hyperparathyroidism

- ❑ Absence of unacceptable toxicity from the drug (e.g. hypocalcemia, upper gastrointestinal bleeding, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease)
- ❑ Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from pretreatment baseline has been submitted
- ❑ Current serum calcium (Ca) >8.4 mg/dL **(labs must be submitted with request)**

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 9/3/2021
REVISED/UPDATED: ~~12/9/2021; 12/23/2021; 02/04/2022;~~ **10/27/2203**