MEDICAL MUTUAL®

Drug Policy

Policy:	Sensipar (cinacalcet) tablets	Annual Review Date: 08/24/2023 Last Revised Date: 08/24/2023

OVERVIEW

Cinacalcet (Sensipar, generic), a calcium-sensing receptor agonist (calcimimetic), is indicated for the following uses: Hypercalcemia in adult patients with parathyroid carcinoma, hypercalcemia in adult patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy and secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on dialysis of coverage.

POLICY STATEMENT

This policy involves the use of Sensipar. Prior authorization is recommended for pharmacy benefit coverage of Sensipar. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sensipar as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sensipar be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: When available, the ICD-9/ICD-10 codes for Malignant Neoplasm of Parathyroid Gland (ICD-9: 194.1* and ICD-10: C75.0*) AND "oncologist or endocrinologist" will be used as part of automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sensipar is recommended in those who meet the following criteria:

1. **Hypercalcemia due to Parathyroid Carcinoma**
   Criteria. *Approve for 1 year if cinacalcet is prescribed by or in consultation with an oncologist or endocrinologist*

2. **Hypercalcemia in Patients with Primary Hyperparathyroidism**
   Criteria. *Approve for 1 year if the following criteria are met:*

A. Patient has failed or is unable to undergo a parathyroidectomy due to a contraindication; AND
B. The medication is prescribed by or in consultation with a nephrologist or endocrinologist

3. Secondary Hyperthyroidism
Criteria. *Approve for 1 year if the following criteria are met:*

A. Patient has kidney disease and is on dialysis; AND
B. The baseline (prior to starting cinacalcet therapy) intact parathyroid hormone (iPTH) level is at least two times the upper limit of normal as defined by the laboratory reference value measured on two separate occasions; AND
C. The medication is prescribed by or in consultation with a nephrologist or endocrinologist

Other Uses with Supportive Evidence

4. Hyperparathyroidism in Post-Renal Transplant Patients
Criteria. *Approve for 1 year if the following criteria is met:*

A. The baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above normal range, as defined by the laboratory reference values; AND
B. The medication is prescribed by or in consultation with a transplant physician, nephrologist or endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sensipar has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Patients with Primary Hyperparathyroidism eligible for Parathyroidectomy.** Parathyroidectomy is the primary treatment for primary hyperparathyroidism.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sensipar® [prescribing information]. Thousand Oaks, CA: Amgen Inc.; December 2019.
2. Crockell YJ. Management of chronic kidney disease: An emphasis on delaying disease progression and treatment options. *Formulary.* 2012;47:228-236.
3. Sharretts JM, Kebebew E, Simonds WF. Parathyroid Cancer. *Semin Oncol.* 2010;37:580-590.
4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD – MBD Work Group, KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney Int Suppl.* 2009;76(Suppl 113):S1-S130.
5. Kidney Disease: Improving Global Outcomes (KDIGO) CKD – MBD Update Work Group. KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney Int Suppl.* 2017;7:1-59.