Original Effective Date: 03/25/2017
Current Effective Date: 09/20/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C9721-A

Sensipar (cinacalcet)

PRODUCTS AFFECTED

Sensipar (cinacalcet), cinacalcet

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Secondary Hyperparathyroidism (HPT) in adult members with chronic kidney disease (CKD) on dialysis, Hypercalcemia in adult members with Parathyroid Carcinoma (PC), Hypercalcemia in adult members with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. PRIMARY HYPERPARATHYROIDISM:

1. Documentation that member has diagnosis of primary hyperparathyroidism
   AND
2. Documentation that member is unable to undergo parathyroidectomy
   AND
3. Documentation that member's serum calcium level (calcium level corrected for albumin) is greater than or equal to 8.4 mg/dL [DOCUMENTATION REQUIRED]
   NOTE: Corrected calcium level = serum calcium + 0.8 (4 - albumin level)

B. SECONDARY HYPERPARATHYROIDISM:

1. Documentation that member has diagnosis of secondary hyperparathyroidism (HPT) in adult members with chronic kidney disease (CKD) on dialysis
   AND
2. Documentation that member is currently receiving regular dialysis treatments
   AND
3. Documentation of failure, contraindication, or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
   AND
4. Documentation that member's serum calcium level (calcium level corrected for albumin) is greater than or equal to 8.4 mg/dL [DOCUMENTATION REQUIRED]
   NOTE: Corrected calcium level = serum calcium + 0.8 (4 - albumin level)
   AND
5. Documented lab results showing an increase in intact parathyroid hormone (iPTH) levels over previous 3-6 months or current labs showing serum iPTH hormone level greater than 300 pg/ml [DOCUMENTATION REQUIRED]
   AND
6. Prescriber attests that cinacalcet will not be used in combination with Parsabiv (etelcalcetide)

C. PARATHYROID CARCINOMA:

1. Documentation that member has diagnosis of hypercalcemia with parathyroid carcinoma (PC)
   AND
2. Documentation that member's serum calcium level (calcium level corrected for albumin) is greater than or equal to 8.4 mg/dL [DOCUMENTATION REQUIRED]
   NOTE: Corrected calcium level = serum calcium +0.8 (4 - albumin level).

D. TERTIARY HYPERPARATHRYOIDISM POST-KIDNEY TRANSPLANT:

1. Documentation that member has diagnosis of tertiary hyperparathyroidism post- kidney transplant
   AND
2. Documentation that member's serum calcium level (calcium level corrected for albumin) is greater than or equal to 8.4 mg/dL [DOCUMENTATION REQUIRED]
   NOTE: Corrected calcium level = serum calcium + 0.8 (4 - albumin level)

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of reduction in serum calcium level from baseline (calcium level corrected for albumin) [DOCUMENTATION REQUIRED]
   AND
2. SECONDARY HYPERPARATHYROIDISM ONLY: Documentation of an improvement from initial authorization of intact parathyroid hormone (iPTH) level [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests or clinical reviewer has found prescriber is monitoring corrected serum calcium levels per labeled recommendations
   Note: Per package insert, for secondary hyperparathyroidism patients with CKD on dialysis, in individuals with a corrected serum calcium below the lower limit of normal but at or above 7.5 mg/dL or with symptoms of hypocalcemia, consider using concomitant therapies to increase corrected

serum calcium. Cinacalcet should be stopped, and hypocalcemia treated if the corrected serum calcium falls below 7.5 mg/dL or patient reports persistent symptoms of hypocalcemia.
AND

4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an oncologist, endocrinologist or nephrologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age or older

QUANTITY:
Secondary Hyperparathyroidism (HPT), Tertiary Hyperparathyroidism: Not to exceed max dose of 180mg per day
Parathyroid Carcinoma (PC): Not to exceed max dose of 360mg per day
Primary HPT: Not to exceed max dose of 360mg per day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Calcimimetic Agent

FDA-APPROVED USES:
Indicated for Secondary Hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
Limitations of Use: Sensipar is not indicated for use in patients with CKD who are not on dialysis because of an increased risk of hypocalcemia

Indicated for hypercalcemia in adult patients with Parathyroid Carcinoma (PC)

Indicated for hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

COMPENDIAL APPROVED OFF-LABELED USES:
Tertiary hyperparathyroidism post-kidney transplant

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

CKD K/DOQI guidelines definition of stages; chronic disease is kidney damage or GFR < 60 mL/minute/1.73 m^2 for ≥3 months:

- Stage 2: GFR 60 to 89 mL/minute/1.73 m^2 (kidney damage with mild decrease GFR)
- Stage 3: GFR 30 to 59 mL/minute/1.73 m^2 (moderate decrease GFR)
- Stage 4: GFR 15 to 29 mL/minute/1.73 m^2 (severe decrease GFR)
- Stage 5: GFR <15 mL/minute/1.73 m^2 or dialysis (kidney failure)

Target range for iPTH: Adults:

- Stage 3 CKD: 35 to 70 pg/mL
- Stage 4 CKD: 70 to 110 pg/mL
- Stage 5 CKD: 150 to 300 pg/mL

Serum phosphorus: Adults:

- Stage 3 and 4 CKD: ≥2.7 to <4.6 mg/dL
- Stage 5 CKD: 3.5 to 5.5 mg/dL

Serum calcium-phosphorus product:

Adults:

- Stage 3 to 5 CKD: <55 mg^2/dL

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Sensipar (cinacalcet) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Sensipar treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL).

OTHER SPECIAL CONSIDERATIONS:

Hepatic function impairment: Use with caution in moderate to severe hepatic impairment (Child-Pugh classes B and C); cinacalcet exposure and half-life are increased; monitor serum calcium, serum phosphorus, and intact parathyroid hormone (iPTH) closely

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:

Cinacalcet HCl TABS 30 MG, 60 MG, 90 MG
Sensipar TABS 30 MG, 60 MG, 90 MG

REFERENCES

1. Sensipar (cinacalcet) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2019.
2. Evenepoel P, Cooper K, Holdaas H, et al: A randomized study evaluating cinacalcet to treat

hypercalcemia in renal transplant recipients with persistent hyperparathyroidism. Am J Transplant 2014; 14(11):2545-2555.
3. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Guideline 13: Treatment of Bone Disease in Chronic Kidney Disease. Available athttp://www2.kidney.org/professionals/KDOQI/guidelines_bone/
4. Marcocci C, Chanson P, Shoback D, et al, "Cinacalcet Reduces Serum Calcium Concentrations in Members with Intractable Primary Hyperparathyroidism," J Clin Endocrinol Metab, 2009, 94(8):2766-72.
5. Moe SM, Cunningham J, Bommer J, et al, "Long-Term Treatment of Secondary Hyperparathyroidism with the Calcimimetic Cinacalcet HCl," Nephrol Dial Transplant,2005
6. Eknoyan G, Levin A, and Levin NW. Bone metabolism and disease in chronic kidney disease. Am J Kidney Dis. 2003;42(4 Suppl 3):1-201.
7. Kidney Disease Improving Global Outcomes. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney International Supplements. June 2017;7(1):1-59. Available at: https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL- Update.pdf. Accessed May 2020.
8. Cozzolino M, Galassi A, et al. Treatment of Secondary Hyperparathyroidism: The Clinical Utility of Etelcalcetide. Ther Clin Risk Manag 2017; 13: 679-689. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5461056/. Accessed May 2020.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Drug Class FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Compendial Approved Off-Labeled Uses Coding/Billing Information	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file