JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS016
		Effective Date	01/01/2006
		Review Date	01/19/2022
	Subject **Sensipar**	*Revision Date*	01/19/2022
		Page	1 of 3

This document applies to the following Participating Organizations:

Priority Partners

Keywords: sensipar

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**2**
IV.	**EXCLUSIONS**	**2**
V.	**REFERENCES**	**2**
VI.	**APPROVALS**	**2**

I. POLICY

A. Sensipar (cinacalcet) will require prior authorization for outpatient prescription drug benefit coverage to ensure proper utilization of this drug product. Sensipar will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Sensipar may be approved for patients meeting the following:
   1. Secondary Hyperparathyroidism (HPT) due to chronic kidney disease(CKD)
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of hyperparathyroidism associated with CKD
         II. Patient is currently undergoing dialysis treatment
         III. Laboratory results show Intact plasma parathyroid hormone (iPTH) level > 400pg/mL [or Bio-Intact (full-length) PTH > 200pg/mL], and one of the following:
            i. Serum calcium level ≥ 8.4 mg/dL
            ii. Calcium X phosphorus product > $55mg^2/dl^2$
         IV. Patient has had trial and inadequate response to both of the following:
            i. one formulary phosphate binder agent (such as calcium acetate [generic of PhosLo], sevelamer [generic of Renagel and Renvela], etc.)
            ii. one vitamin D analog (such as calcitriol, Doxercalciferol [generic of Hectorol], etc.)
   2. Parathyroid Carcinoma
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of hypercalcemia associated with parathyroid carcinoma

II. Laboratory results show total serum calcium level (corrected for serum albumin) ≥ 10.2 mg/dL (or maximum per lab/facility) despite standard therapy to control hypercalcemia

3. Primary Hyperparathyroidism (HPT)
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing the following
      I. Patient has a diagnosis of hypercalcemia associated with primary HPT
      II. Laboratory results show total serum calcium level (corrected for serum albumin) ≥ 10.2 mg/dL (or maximum per lab/facility) despite standard therapy to control hypercalcemia
      III. Patient is not able to undergo parathyroidectomy

*Calculation for corrected total serum calcium:

1. Total calcium + 0.8 (4 – serum albumin) [4gm/dl (normal serum albumin) – most recent serum albumin]
2. The normal serum albumin of 4.0gm/dl is based on measurements using bromocresol green. If the bromocresol purple method is used, the normal serum albumin should be 3.5mg/dl.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval may be given for 3 months.
B. Approval can be extended for 6 months, then 12 months thereafter for members who meet the following criteria:
   1. For Secondary HPT:
      1. Documentation of Intact PTH levels >150pg/mL and serum calcium >8.4
      2. Documented reduction in PTH while the patient is still undergoing dialysis for CKD
   2. For parathyroid carcinoma and primary HPT:
      1. Documented reduction in serum calcium levels

IV. EXCLUSIONS

A. Sensipar will not be approved for the following:
   1. Pediatric patients
   2. Patients with CKD that are not on dialysis
   3. Initiation of therapy if the patient's serum calcium is less than the lower limit of the normal range
   4. Any indications or uses that are not FDA-approved or guideline-supported.
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Sensipar [prescribing information]. Thousand Oaks, CA: Amgen; December 2019.
2. Quarles, LD, Berkoben, M. Management of secondary hyperparathyroidism in adult dialysis patients. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on 12/10/2021.
3. 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 (2011). 2017 Jul;7(1):1-59.

VI. APPROVALS

Signature on file at JHHC

JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS016
		Effective Date	01/01/2006
		Review Date	01/19/2022
	Subject **Sensipar**	*Revision Date*	01/19/2022
		Page	3 of 3

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Changed format-Removed Background and sources, removed process of initiation of request
07/27/2017	Updated Exclusion section regarding physician samples
07/01/2018	Removed EHP Line of Business
01/19/2022	Updated clinical criteria section

Review/Revision Dates: 1/14/2009, 3/01/2014, 4/20/2016, 07/27/2017, 05/01/2018, 07/01/2018, 01/19/2022