

Medical Policy: Parsabiv® (etelcalcetide)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.155	January 23, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Parsabiv mimics calcium binding to the calcium-sensing receptor (CaSR) on chief cells of the parathyroid gland, which activates the receptor and decreases secretion of parathyroid hormone

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 45 mg per 7 days

Guideline

I. Initial Approval Criteria

Parsabiv may be considered medically necessary if the below condition is met **AND** use is consistent with the medical necessity criteria that follows:

1. Secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis

- A. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **AND**
- B. Patient is on dialysis; **AND**
- C. **All** of the following;
 - i. Patient is 18 years of age or older; **AND**
 - ii. History of failure, contraindication, or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.); **AND**
 - iii. History of failure, contraindication, or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.); **AND**
 - iv. History of failure of maximum tolerated dosage, adverse reaction, or contradiction to Sensipar (cinacalcet hydrochloride); **AND**
- D. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **AND**
- E. Prescribed by or in consultation with an endocrinologist or nephrologist

Limitations/Exclusions

- 1. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

- 1. Patient continues to meet INITIAL APPROVAL CRITERIA

Dosage/Administration

Indication	Dose
Secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis	Initial, 5 mg IV bolus 3 times per week administered at the end of hemodialysis; adjust in 2.5 or 5 mg increments every 4 weeks to maintain target parathyroid hormone levels and normal serum calcium levels; MAX 15 mg 3 times per week

Applicable Procedure Codes

Code	Description
J0606	Injection, etelcalcetide, 0.1 mg, 1 billable unit = 0.1 mg

Applicable NDCs

Code	Description
55513-0740-xx	Parsabiv 2.5mg/0.5mL Solution
55513-0741-xx	Parsabiv 5mg/mL Solution
55513-0742-xx	Parsabiv 10mg/2mL Solution

ICD-10 Diagnoses

Code	Description
E83.51	Hypocalcemia
N18.6	End stage renal disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/23/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	5/23/2023	Annual Revision: no criteria changes
EmblemHealth & ConnectiCare	09/20/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	03/30/2020	Annual Review: added 18 years of age and older to Initial Approval Criteria.

References

1. Parsabiv [prescribing information]. Thousand Oaks, CA; Amgen/KAI Pharmaceuticals; February 2017.