Etelcalcitide

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-32	**Version Control:** Version No.1.0	**Effective Date:** 28/01/2024	**Revision Date:** 28/01/2025
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** N/A		

Table of Contents

1. Abstract

1.1 For Members

Etelcalcitide is a medication used to treat secondary hyperparathyroidism in adult patients with chronic kidney disease who are on dialysis. Hyperparathyroidism is a condition that is caused when the parathyroid glands located in the neck make too much parathyroid Hormone. It is a prescription medication that should be given only by or under the direct supervision of your doctor.

1.2 For Medical Professionals

Etelcalcitide injection is in a class of medications called calcimimetics. It works by signalling the body to produce less parathyroid hormone to decrease the amount of calcium in the blood, used to treat increased amounts of parathyroid hormone with long term kidney disease patients who are dependent on renal dialysis.

2. Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details of Etelcalcitide as per policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Etelcalcitide is a medication used to treat secondary hyperparathyroidism in adult patients with chronic kidney disease who are on dialysis.

TREATMENT EVALUATION

- Ensure corrected serum calcium is equal to or above the lower limit prior to initiation, dose optimizing, or re-initiation.
- Measure PTH after 4 weeks from initiation or dose correction.
- Electrolytes should be monitored at a frequency appropriate for the underlying disease, typically measured every 3 months for dialysis patients.
- If the corrected serum calcium falls below the normal limit, stop Etelcalcitide and treat hypocalcaemia or patients report symptoms of hypocalcaemia.

Test	Reference range
Serum calcium	<2.10 mmol/L (<8.4mg/dL)
Serum intact parathyroid hormone (iPTH)	>88 ng/L (>88 picograms/mL)
Serum creatinine	>91.5 µmol/L (>1.2 mg/dL) in CKD
Serum urea	>7.14 mmol/L (>20 mg/dL) in CKD

DOSAGE AND ADMINISTRATION

- The recommended starting dose is 5 mg administered by intravenous bolus injection three times a week at the end of haemodialysis treatment.
- The maintenance dose is adjusted and determined by titration based on parathyroid hormone (PTH) and corrected serum calcium response. The dose range is 2.5 to 15 mg three times per week.
- The dose may be increased by 2.5 mg or 5 mg, at least 4 weeks from the last infusion.

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible clinician specialities

Eligible clinician speciality
Internal Medicine
Endocrinology/Metabolic Medicine
Nephrology
Cardiology
Critical Care

3.3 Non-Coverage

Visitor plan

3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC 004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
MNEC 003	Service is not clinically indicated based on good clinical practice
AUTH-001	Prior approval is required and was not obtained
MNEC-005	Service/supply may be appropriate, but too frequent
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender

5. Appendices

5.1 References

https://www.medicines.org.uk/emc/product/4417
label (fda.gov)
Parsabiv | European Medicines Agency (europa.eu)
Secondary hyperparathyroidism - Investigations | BMJ Best Practice

5.2 Revision History

Date	Change(s)
28/01/2024	New version