# Etelcalcitide

## Adjudication Guideline

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|---|---|---|---|---|
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| Daman | Pharmaceutical Standards & Governance | N/A |

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# 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**

- Initiation of this medication only for one month as per DOH guideline
- 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.

**Red flags:**

- Cinacalcet consider as Alternative Therapy indicated for treatment of 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
- transitioning to cinacalcet in cases where Etelcalcetide is not tolerated or when oral administration is preferred. Transition decisions should be guided by calcium levels, PTH trends, and patient-specific factors.
- Monitor for QT interval prolongation, especially in the presence of hypocalcemia. Correct serum calcium levels prior to initiating therapy and during treatment to mitigate cardiac risk.
- Cinacalcet is contraindicated in pediatric patients under 18 years

## 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
label


## 5.2 Revision History

| Date | Version No. | Change(s) |
|---|---|---|
| 28/01/2024 | V1.0 | New version |
| 7/11/2024 | V2.0 | No changes/ updated in the new format |
| 28/11/22025 | V3.0 | Add clinical alternatives (cinacalcet) |
| 19/10/2026 | V3.1 | No changes |


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