Sample Letter of Medical Necessity for Parsabiv® (etelcalcetide)

Note: This sample letter is provided as a courtesy for physicians to consider when they are preparing letters of medical necessity for their patients. It is not intended to direct the physician on what should be included in such a letter. Physicians should exercise their independent medical judgment and discretion in appropriately diagnosing and characterizing the individual patient's medical condition and history. As always, providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement. Please delete this paragraph and heading above, and delete or revise all blue text below, when preparing an actual letter.

[Physician/Practice Letterhead]

[Date]

[Facility Name]

[Facility Address]

RE: Coverage of Parsabiv® (etelcalcetide)

[Patient Name]

[Date of Request]

[Date of Denial]

Attention: [P&T Department]

Dear [Name of P&T member],

I am writing on behalf of my patient, [Patient Name]

Parsabiv® (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Limitations of Use
Parsabiv® has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Please see the full Important Safety Information below.

[If a prior authorization form has been submitted previously, indicate the date of submission and the outcome].

Based on the FDA-approved indication, I strongly believe that treatment with Parsabiv® is required. Parsabiv® is medically necessary for [patient's name] as documented by:
[Include the bullets below where the patient's medical history supports them]

- History of uncontrolled sHPT [Based on your clinical judgement, you may wish to describe the patient's history of PTH, P and Ca labs, vit D and oral cinacalcet use over the last 3 months]
- This patient is not a surgical intervention candidate.

In my clinical opinion, [patient's name] should receive Parsabiv® for the following reasons:
[List reasons]

In summary, based on my clinical opinion, Parsabiv® is medically necessary for [patient's name].

Please call me directly at [office phone number] if I can provide you with any additional information you need in order to approve my request.

Sincerely,
[Physician's name]

[List enclosures as appropriate: Examples of enclosures may include excerpt(s) from patient's medical record, relevant treatment guidelines, and product prescribing information.]

Important Safety Information for Parsabiv®(etelcalcetide)

Contraindication: Parsabiv® is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Hypocalcemia: Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Concurrent administration of Parsabiv® with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to Parsabiv® should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv®. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv®. Once the maintenance dose has been established, measure PTH per clinical practice.

Worsening Heart Failure: In Parsabiv® clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv® for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding: In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv®.

Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv®. Monitor patients for worsening of common Parsabiv® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® therapy.

Adynamic Bone: Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions: In clinical trials of patients with secondary HPT comparing Parsabiv® to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

Please see the full Prescribing Information

Report adverse events related to any Amgen product to Amgen by calling 800-77-AMGEN (800-772-6436) if you reside in the U.S.

USA-416-81278