



Therapeutic Class ReviewSM

Hormones

Hyperparathyroidism Products -- Cinacalcet HCl (SensiparTM)

April 2005

New Product for Review

Cinacalcet HCl (SensiparTM) (Amgen)

Dossier Provided by Manufacturer: yes

Quality of Dossier: 2

1. Low quality (dossier w/missing components)
2. Medium quality (all components, except pharmacoeconomic model)
3. High quality (all components, well done)

Executive Summary

- Cinacalcet HCl (SensiparTM) is a unique, orally active medication, which increases the sensitivity of calcium receptors; thereby inhibiting parathyroid hormone (PTH) secretion.
- There is compelling evidence supporting the medical value for cinacalcet (SensiparTM) in patients with secondary hyperparathyroidism (SHPT) due to end stage renal disease (ESRD):
 - At doses > 90mg/day, consistently lowers serum PTH, and
 - Reduces serum calcium (Ca), phosphorus (P), and the Ca x P product.
- Medications, such as phosphate binders, correct some of the serum Ca and P imbalances resulting from SHPT, but over time may not overcome the overall imbalances due to elevated PTH and worsening of disease.
- The safety and efficacy of cinacalcet HCl (SensiparTM) for lowering serum Ca in individuals with parathyroid carcinoma, or intractable primary hyperparathyroidism has not been established.
 - Well-designed studies with adequate power are lacking given the limited patient population to conduct studies.
 - These patients have limited treatment choices.
- Nausea and vomiting are the predominant adverse effects that cause discontinuation of treatment.
- Post marketing experience indicates that cinacalcet HCl (SensiparTM) may potentiate seizures in susceptible end-stage renal disease (ESRD) patients, or can also cause hypocalcemia.

Decision

Add cinacalcet HCl (SensiparTM) to the formulary/preferred medication list because there is good evidence to support its clinical value in managing SHPT.

Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	Potential Off-Label Use(s)
Cinacalcet HCl (Sensipar™)	3/08/2004	1. Treatment of secondary hyperparathyroidism in patients with Chronic Kidney Disease on dialysis. 2. Treatment of hypercalcemia in patients with parathyroid carcinoma.	Oral	Primary Hyperparathyroidism. ^[1]

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