



## Therapeutic Class Review<sup>SM</sup>

### Cinacalcet HCl (Sensipar<sup>TM</sup>)

April 2005

#### New Product for Review

Cinacalcet HCl (Sensipar<sup>TM</sup>) (Amgen)

Dossier Provided by Manufacturer: yes

#### Available Therapeutic Alternative(s)

Preferred/Formulary	Non-Preferred/Non-Formulary
None	None

#### Executive Summary

- Cinacalcet HCl (Sensipar<sup>TM</sup>) 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 (Sensipar<sup>TM</sup>) 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 (Sensipar<sup>TM</sup>) 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 (Sensipar<sup>TM</sup>) may potentiate seizures in susceptible ESRD patients, or can also cause hypocalcemia.

#### Conclusion

Cinacalcet HCl (Sensipar<sup>TM</sup>) is a formulary/preferred medication 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	AWP Cost*	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	30mg \$10 60mg \$20 90mg \$30  \$1200-1800/month  @ 120-180mg/day	Primary Hyperparathyroidism. <sup>[1]</sup>

\*AWP (average wholesale price) based on First Data Bank as of November 24, 2004.

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