



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

### Paricalcitol (Zemlar<sup>®</sup>)

February 2006

#### New Product(s) for Review

paricalcitol (Zemlar<sup>®</sup>) [Abbott Laboratories]

#### Executive Summary

- Active Vitamin D analogs (calcitriol, paricalcitol (Zemlar) and doxercalciferol (Hectorol) are used to control the build-up of PTH resulting from CKD.
  - Injectable forms of Vitamin D analogs are used in end stage renal disease (ESRD) or Stage 5 CKD patients on dialysis because these patients are likely to need treatment for SHPT and have a dialysis catheter making administration of the injectable forms more practical.
  - Oral forms are generally used in treating patients with moderate to severe CKD (Stages 3 to 4) not yet requiring dialysis.

#### Evidence

- There is uncertain evidence that paricalcitol (Zemlar) or doxercalciferol (Hectorol) compared to placebo provides clinically relevant reductions in PTH levels in the treatment of secondary hyperparathyroidism (SHPT) from:
  - Stage 3 and 4 Chronic Kidney Disease (CKD)
  - End-stage renal disease (ESRD)
- There is no long-term data that paricalcitol (Zemlar) or doxercalciferol (Hectorol) prevents adverse consequences of SHPT (increased fracture risk, vascular calcification, and cardiovascular disease) in patients with Stage 3 and 4 CKD or ESRD receiving dialysis.
- There is no useful evidence that shows paricalcitol (Zemlar) or doxercalciferol (Hectorol) provides greater efficacy or a more favorable safety profile than calcitriol in reducing parathyroid hormone levels in Stage 3 and 4 CKD and/or ESRD.
- Claims that paricalcitol (Zemlar<sup>®</sup>) or doxercalciferol (Hectorol) are safer, less hypercalcemic, or less hyperphosphatemic than calcitriol are unsubstantiated.

## Decision

- Paricalcitol (Zemplar) is non-formulary/non-preferred because it provides no additional value relative to other established medication options for the treatment of SHPT in patients with Stage 3 and 4 CKD or ESRD.
- Doxercalciferol (Hectorol) is non-formulary/non-preferred because it no longer provides clinical value for its additional cost due to generic availability of calcitriol.

## Products<sup>1, 11, 12</sup>

Drug Product	Date of FDA Approval	FDA Approved Indication(s)			Oral Dosing Regimen	Potential Off-Label Use(s) <sup>c</sup>
		Patients with secondary hyperparathyroidism		Management of hypocalcemia in postsurgical, idiopathic or pseudo-hypoparathyroidism		
		w/ CKD on dialysis	CKD (no dialysis)			
paricalcitol (Zemplar)	4/17/98  5/26/05	IV form only	Stage 3 & 4	--	--  1- 2 mcg/daily or 2 – 4 mcg three times weekly.	Patients with ESRD (Stage 5 CKD) on dialysis (oral) with dosing up to 32mcg three times weekly.
calcitriol	8/17/78 <sup>a</sup>	yes	yes	yes	0.25 – 1mcg daily  0.25 – 0.5 mcg daily  0.25 – 2 mcg daily	Vitamin D-dependent rickets  Vitamin D-resistant rickets (familial hypophosphatemia)
doxercalciferol (Hectorol)	06/09/99	yes	Stage 3 & 4	--	10 – 20 mcg three times weekly  1 – 3.5 mcg daily	--

<sup>a</sup> Date applies to approval date for the original brand name medication where there are now generics available.

<sup>b</sup> Cost estimate based on AWP (average wholesale price) listed in First Data Bank or MAC (maximum allowable cost) as of September 2005 for 1 month of therapy.

<sup>c</sup> As listed in ©1974 - 2005 Thomson MICROMEDEX database or as referenced.

## References

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