

Medical Policy Manual **Approved: Do Not Implement Until 12/12/09**

Dexamethasone Intravitreal Implant

DESCRIPTION

Dexamethasone is a potent corticosteroid shown to suppress inflammation by the inhibition of multiple inflammatory cytokines. Delivery of dexamethasone into the vitreous body is facilitated when packaged in a single use solid polymer drug delivery system for injection.

An example of a preparation of a dexamethasone intravitreal implant is Ozurdex™.

REFER TO DECISION SUPPORT TREE

POLICY

- A dexamethasone intravitreal implant for the treatment of macular edema is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- A dexamethasone intravitreal implant for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

- A dexamethasone intravitreal implant for the treatment of macular edema is considered **medically appropriate** with **ANY ONE** of the following:
 - Post branch retinal vein occlusion (BRVO)
 - Post central retinal branch occlusion (CRVO)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

No controlled studies were found in the published literature that validate the use of dexamethasone intravitreal implant for any other conditions/diseases.

SOURCES

MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2009) *Dexamethasone*. Retrieved July 14, 2009 from MICROMEDEX Healthcare Series.



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Policy

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U. S. Food and Drug Administration. (2009, June). Center for Drug Evaluation and Research. *Ozurdex™ (dexamethasone intravitreal implant)*. Retrieved July 15, 2009 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022315lbl.pdf

U. S. Food and Drug Administration. (2009, June). Center for Drug Evaluation and Research. *Ozurdex™ (dexamethasone intravitreal implant) approval letter*. Retrieved July 15, 2009 from http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022315s000ltr.pdf

EFFECTIVE DATE 12/12/2009

ID_BT



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Pharmaceutical Decision Support Tree

Dexamethasone Intravitreal Implant (Ozurdex™)

1. Does the individual have a diagnosis of macular edema?

If yes, go to question # 2

If no, this does not meet medical necessity and/or medical appropriateness criteria

2. Has the individual experienced any one of the following?

- Branch retinal vein occlusion (BRVO)
- Central retinal branch occlusion (CRVO)

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, this does not meet medical necessity and/or medical appropriateness criteria