BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 08/26/10
LAST REVIEW DATE: 04/29/14
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

INTRAVITREAL IMPLANTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

An intravitreal implant is a surgically implanted drug delivery system in the vitreous of the eye for sustained release of drug to the posterior eye segment. Various intravitreal implants have been investigated for treatment of numerous inflammatory eye conditions.

FDA approved implants include:

- Cytovene-IV (ganciclovir)
- Ozurdex® (dexamethasone)
- Retisert® (fluocinolone acetonide)
- Vitrasert® (ganciclovir)

INTRAVITREAL IMPLANTS (cont.)

Criteria:

- Dexamethasone intravitreal implant (Ozurdex®) is considered ***medically necessary*** with documentation of **ANY** of the following indications:

  1. Macular edema following branch retinal vein occlusion or central retinal vein occlusion
  2. Non-infectious ocular inflammation, or uveitis, affecting the intermediate or posterior segment of the eye

- Fluocinolone acetonide intravitreal implant (Retisert®) for the treatment of chronic noninfectious intermediate, posterior or panuveitis in one or both eyes is considered ***medically necessary***.

- Ganciclovir intravitreal implant (Cytovene, Vitrasert®) is considered ***medically necessary*** with documentation of **ANY** of the following indications:

  1. CMV retinitis in an immunocompromised individual, including individuals with HIV
  2. Transplant recipients at risk for CMV disease

- Intravitreal implants for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

INTRAVITREAL IMPLANTS (cont.)

Resources:

1. 9.03.23 BCBS Association Medical Policy Reference Manual. Intravitreal Corticosteroid Implants. Re-issue date 03/13/2014, issue date 06/10/2010

FDA Product Approval Information for Ganciclovir (Cytovene, Vitrasert®):

- FDA-approved indication: For the treatment of CMV retinitis in immunocompromised patients, including patients with acquired immunodeficiency syndrome (AIDS). For the prevention of CMV disease in transplant recipients at risk for CMV disease.

FDA Product Approval Information for Ozurdex®:

- FDA-approved indication: For the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

  For the treatment of non infectious uveitis affecting the posterior segment of the eye.

FDA Product Approval Information for Retisert®:

- FDA-approved indication: For the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.