INTRAVITREAL IMPLANTS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
INTRAVITREAL IMPLANTS (cont.)

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:

- Iluvien® (fluocinolone acetonide)
- Ozurdex® (dexamethasone)
- Retisert® (fluocinolone acetonide)

Criteria:

- Dexamethasone intravitreal implant (i.e., Ozurdex) is considered medically necessary with documentation of ANY of the following indications:
  1. Macular edema following branch or central retinal vein occlusion
  2. Non-infectious ocular inflammation, or uveitis, affecting the intermediate or posterior segment of the eye
  3. Diabetic macular edema

- Fluocinolone acetonide intravitreal implant is considered medically necessary with documentation of ANY of the following indications:
  1. Chronic noninfectious intermediate, posterior or panuveitis in one or both eyes (Retisert)
  2. Diabetic macular edema in individuals who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (Iluvien)
INTRAVITREAL IMPLANTS (cont.)

Criteria: (cont.)

➢ 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.

These indications include, **but are not limited to:**

- Birdshot retinochoroidopathy
- Circumscribed choroidal hemangiomas
- Cystoid macular edema related to retinitis pigmentosa
- Idiopathic macular telangiectasia type 1
- Postoperative macular edema
- Proliferative vitreoretinopathy
- Radiation retinopathy

Resources:

Literature reviewed 04/17/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

INTRAVITREAL IMPLANTS (cont.)

Resources: (cont.)

Iluvien Package Insert:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iluvien contains a corticosteroid and is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.</td>
<td>For ophthalmic intravitreal injection. Iluvien is a non-bioerodable intravitreal implant in a drug delivery system containing 0.19 mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25 µg/day and lasting 36 months.</td>
</tr>
</tbody>
</table>

Ozurdex Package Insert:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)</td>
<td>For ophthalmic intravitreal injection. Intravitreal implant containing dexamethasone 0.7 mg in the NOVADUR® solid polymer drug delivery system.</td>
</tr>
<tr>
<td>Non-infectious uveitis affecting the posterior segment of the eye</td>
<td></td>
</tr>
<tr>
<td>Diabetic macular edema</td>
<td></td>
</tr>
</tbody>
</table>
INTRAVITREAL IMPLANTS (cont.)

Resources: (cont.)

Retisert Package Insert:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retisert is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.</td>
<td>Retisert (flucinolone acetonide intravitreal implant) 0.59 mg is implanted into the posterior segment of the affected eye through a pars plana incision. The implant contains one tablet of 0.59 mg of fluocinolone acetonide. Retisert is designed to release fluocinolone acetonide at a nominal initial rate of 0.6 µg/day, decreasing over the first month to a steady state between 0.3-0.4 µg/day over approximately 30 months. Following depletion of fluocinolone acetonide as evidenced by recurrence of uveitis, Retisert may be replaced.</td>
</tr>
</tbody>
</table>
INTRAVITREAL IMPLANTS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah nilínígíí Blue Cross Blue Shield of Arizona haada yít’égé bínà’idíldkígo éí doodago Háida bíjá anileéedígíí t’áadoo le’é yina’idíldkígo beehaz’áanii hólq díí t’àa hazaak’ehí háká a’doowolgo bee hazz’á doo bąqih ilinígóó. Atá’ halné’ígíí kojí bíchį’ hodîllinííííí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو تأتي شخص تساعد اسم، يخص Blue Cross Blue Shield of Arizona المساعدة والمعلومات الضرورية لتغطية من دون أي تكلفة للتحدث مع مرسل التصلب ب. 877-475-4799

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INTRAVITREAL IMPLANTS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinitutusan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makaasap ang isang tagasal, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 문해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 이용 부담없이 온라인 수 있는 권리가 있습니다. 그렇게 통해 역시와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の親の図りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

آگر شما یا کسی که شما به او کمک می‌کنید، سوالاتی در مورد اطلاعات به زبان خود را به شرکت رایگان دریافت نمایید 877-475-4799.

Assyrian:

Blue Cross Blue Shield of Arizona ئاسف بگو و گەرگە ە stakeholders، مەنەکەکەرە دەستبەردەیە، ئەمەشەکە لە 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kom Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: ถ้าคุณหรือผู้ช่วยคุณมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถติดต่อได้โดยไม่เสียราย ที่ติดต่อ 877-475-4799.