BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Conjunctival Incision with Posterior Juxtascleral Placement of Anecortave Acetate Depot Suspension

Policy #: 254
Category: Ophthalmology

Latest Review Date: March 2021
Policy Grade: **Effective October 1, 2009: Active Policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Policy:

Blue Advantage will treat **conjunctival incision with posterior juxtascleral placement of Anecortave Acetate Depot Suspension** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Anecortave acetate (Retaane) (Alcon, Inc.) is an angiostatic steroid under investigation for the prevention and treatment of ocular diseases, in particular age-related macular degeneration (ARMD). It is administered with a blunt-tipped, curved cannula as a posterior juxtascleral depot. The curved cannula follows the surface of the sclera, without puncturing the globe. Once the cannula is in place, anecortave acetate is injected in the juxtascleral space (behind the eye) overlying the macula and the drug is slowly released to the choroid over a six-month period. This novel method of drug delivery is intended to avoid the risk of intra-ocular infection and retinal detachment, the most common side effects associated with injecting therapeutic agents directly into the eye, and it requires less frequent dosing compared to other drugs.

Advantages to the posterior juxtascleral placement of a pharmacologic agent may include reduced risk for retinal detachment, endophthalmitis and other safety issues associated with repeated intravitreal injections (a common route of administration for pharmaceutical agents in the treatment of ocular disorders).

KEY POINTS:

This policy is reviewed regularly with the most recent literature review performed through March 23, 2021.

Summary of Evidence

The ocular delivery of anecortave acetate was tested in preclinical and clinical pharmacokinetic and metabolism studies. Results of initial studies led to the design of a new cannula that could effectively deliver anecortave acetate as a posterior juxtascleral depot, providing adequate retinal and choroidal drug concentrations for up to six months after a single administration. A counter-pressure device was designed to prevent drug reflux during and immediately after posterior juxtascleral depot administration. Pharmacokinetic studies support the effectiveness of these devices. Anecortave acetate is rapidly hydrolyzed by esterases to pharmacologically active anecortave desacetate, and is further reductively metabolized to one major and several minor products that circulate as glucuronide conjugates. Low levels of these anecortave acetate metabolites were detectable for only approximately two weeks in the plasma after a 15-mg posterior juxtascleral depot administration to age-related macular degeneration patients. Studies show that posterior juxtascleral depot administration of anecortave acetate is an effective,

minimally invasive method of delivering this drug to the choroid and retina. However, randomized controlled studies are needed to determine its clinical utility compared to the standard of care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements
None identified.

KEY WORDS:
Macular degeneration, Conjunctival incision, posterior juxtascleral placement of Anecortave Acetate Depot Suspension, Anecortave Acetate Depot Suspension, Retaane®, angiostatic cortisone, age-related macular degeneration, anecortave acetate, posterior juxtascleral depot, retina

APPROVED BY GOVERNING BODIES:
Not applicable.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

68399	Unlisted procedure, conjunctiva

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, October 2005
Available for comment October 28-December 12, 2005
Medical Policy Group, September 2007
Medical Policy Group, March 2009
Medical Policy Group, October 2009
Policy no longer reviewed effective October 1, 2009
Medical Policy Group, December 2014
Medical Policy Group, November 2019
Medical Policy Group, March 2021
