
Medical Policy



Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Category: Surgery

***Current Policy Effective Date: 7/1/09**

Title: Conjunctival Incision with Posterior Extrasceral Placement of a Pharmacologic Agent

****Procedure Code(s): 0124T**

Description/Background

Many new pharmacologic agents promoting angiostasis for the treatment of age-related macular degeneration are in development, e.g., anecortave acetate (Retaane®) for depot suspension. Anecortave acetate is synthetic cortisone that has been chemically modified into an angiostatic cortisone that inhibits the proteolysis required for vascular endothelial cell migration, thereby inhibiting ocular neovascularization. Anecortave acetate is a slow-release depot suspension that may be delivered at 6-month intervals and allows for sustained delivery to the affected area near the macula when administered by the novel procedure of posterior extrascleral (juxtasceral) placement. Retaane® received an approval letter from the Food and Drug Administration (FDA) in May 2005 for treatment of age-related macular degeneration but has not yet received final FDA approval.

The procedure of conjunctival incision with posterior extrascleral placement of the depot suspension involves creating a 1.0-1.5mm to 2-3mm incision into the superotemporal quadrant of the orbit. The incision is 8 mm posterior to the limbus between the superior and lateral rectus muscle insertions. The incision is made down through the conjunctiva and Tenon's capsule to reveal bare white sclera but the sclera is not incised. A specially-designed, blunt-tipped, curved 56° cannula is then carefully inserted into the juxtasceral (episcleral) plane between the outer surface of the sclera and Tenon's capsule and fed forward until the cannula tip is near the macula. Gentle pressure is applied around the inserted cannula during administration of the depot suspension and during the removal of the cannula to prevent reflux. A semi-pressure patch is then applied.

*See policy history boxes for any previous effective dates if applicable

**See section "CPT/HCPCS Level II Codes and Description" for code nomenclature and for additional code(s) if applicable.

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BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.

Conjunctival Incision with Posterior Extrasceral Placement of Pharmacological Agent.RK.Is.070109.EI

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

CPT/HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0124T Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)

Diagnoses/Medical Conditions

- Age-related macular degeneration
 - Subfoveal choroidal neovascularization
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Medical Policy Statement

Conjunctival incision with posterior extrascleral placement of a pharmacologic agent, e.g., anecortave acetate depot suspension, is experimental/investigational. This procedure has not yet received final approval from the Food and Drug Administration (FDA). Additionally, there are currently no studies available on the long-term health outcomes of this procedure and it has not been determined to be as safe and effective as currently available treatments.

Rationale

The procedure of conjunctival incision with posterior juxtascleral placement of a pharmacologic agent, e.g., anecortave acetate depot suspension has been performed over 350 times in 128 patients with subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (ARMD) in the Anecortave Acetate Clinical Study Group. The Anecortave Acetate Clinical Study, a blinded, randomized controlled trial, was conducted at 18 clinical sites in the United States and the European Union, followed patients for two years and was completed in June 2003. Some patients in the study had this procedure performed several times in the same superotemporal quadrant, including four times in 48 patients and at least two times in 81 patients. No serious clinically relevant treatment-related safety issues were reported from either the study medication (anecortave acetate) or the procedure for administration. The two most observed adverse events were cataracts and

decreased visual acuity (≥ 4 logMAR lines or ≥ 20 logMAR letters), which occurred in both study and placebo groups at similar rates. Cataracts were found in 27% and 30% and decreased visual acuity was noted in 25% and 30% in the treatment and placebo groups, respectively. These occurrences included study eyes, untreated eyes or both eyes and are commonly experienced in patients with ARMD. Other adverse events that were reported as mild and transient included ptosis, ocular pain, visual abnormalities (e.g., hazy vision, black spots, light flashes), subconjunctival hemorrhage and ocular pruritus.

Conjunctival incision with posterior juxtascleral placement of anecortave acetate depot suspension or placebo appeared to be technically feasible and clinically safe in this study of 128 patients. The adverse events reported were mostly mild and transient and were commonly experienced with ocular procedures.

An October 2005 TEC special report on the treatment of age-related macular degeneration supports the above conclusions. The special report noted that although suggestive, the results of the Anecortave Acetate Clinical Study Group lacked robustness. The trial was only partially blinded and censoring was substantial. No dose-effect was evident with 15 mg being superior to placebo and 30 mg being the least efficacious. The analytical approach to missing data was suboptimal, and whether assumptions of repeated measures analysis of variance (ANOVA) were met (correlations equal over time) was unstated. Finally, adverse events, even transient, were frequent among both treated and placebo groups.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

Conjunctival incision with posterior extrascleral placement of a pharmacologic agent, e.g., anecortave acetate depot suspension, is experimental/investigational. This procedure has not yet received final approval from the Food and Drug Administration (FDA). There are no studies available on the long term health outcomes of this procedure. It has not been determined to be as safe and effective as currently available treatments.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

Related Policies

- Visudyne (Verteporfin) Photodynamic Therapy
- Pegaptanib Sodium Injection (Macugen) for the Treatment of Age-Related Neovascular Macular Degeneration (ARMD)
- Photocoagulation for Macular Drusen

Medicare Information

There is currently no national or local Medicare coverage determination on this procedure. However, the service is payable under OPPS and Medicare would review requests for this procedure on a case-by-case basis.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Augustin, A. J., et al., "Safety of posterior juxtasclear depot administration of the angiostatic cortisone anecortave acetate for treatment of subfoveal choroidal neovascularization in patients with age-related macular degeneration," *Graefes Archive for Clinical and Experimental Ophthalmology*, Vol. 243, No. 1, 2005, pp. 9-12.
 - Blue Cross Blue Shield Association, "Conjunctival Incision with Posterior Juxtasclear Placement of Anecortave Acetate Depot Suspension," *Medical Policy Reference Manual*, Policy #9.03.16, Original Policy Date, September 2005, Last Review Date, April 2007.
 - Blue Cross Blue Shield Association, "Current and Evolving Strategies in the Treatment of Age-Related Macular Degeneration," *Technology Evaluation Center (TEC) Bulletin*, Vol. 22, No. 3, October 2005, pp. 18-20.
 - D'Amico, D. J., et al., "Anecortave Acetate as Monotherapy for Treatment of Subfoveal Neovascularization in Age-related Macular Degeneration: Twelve-Month Clinical Outcomes," *Ophthalmology*, Vol. 110, No. 12, 2003, pp. 2372-2385.
 - D'Amico, D. J., et al., "Anecortave Acetate As Monotherapy For The Treatment of Subfoveal Lesions In Patients With Exudative Age-Related Macular Degeneration (AMD): Interim (Month 6) Analysis of Clinical Safety and Efficacy," *Retina*, Vol. 23, No. 1, 2003, pp. 14-23.
 - Geltzer, A., et al., "Surgical implantation of steroids with antiangiogenic characteristics for treating neovascular age-related macular degeneration," *Cochrane Database of Systematic Reviews*, 2007, Issue 4, Article No. CD005022.
 - HAYES Medical Technology Brief, "Retaane® (anecortave acetate for depot suspension) (Alcon Research Ltd.) for Wet Age-Related Macular Degeneration," Lansdale, PA, HAYES, Inc., April 3, 2005, updated May 13, 2007.
 - Regillo, C. D., MD, et al., "Clinical Safety Profile of Posterior Juxtasclear Depot Administration of Anecortave Acetate 15mg Suspension as Primary Therapy of Adjunctive Therapy with Photodynamic Therapy for Treatment of Wet Age-Related Macular Degeneration," *Survey of Ophthalmology*, Vol. 52, Supp. 1, January 2007, pp. S70-S78.
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Medical Policy Title: Conjunctival Incision with Posterior Extrascleral Placement of a Pharmacologic Agent

- Slakter, J. S., et al., "Anecortave acetate (15 milligrams) versus photodynamic therapy for treatment of subfoveal neovascularization in age-related macular degeneration," *Ophthalmology*, Vol. 113, No. 1, 2006, pp. 3-13.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/19/09, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/08	3/6/08	5/1/08	Joint policy established
7/1/09	4/21/09	4/21/09	Routine Maintenance

Next Review Date: 2nd Qtr, 2010

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CONJUNCTIVAL INCISION WITH POSTERIOR EXTRASCLERAL PLACEMENT OF A
PHARMACOLOGICAL AGENT

I. Short Description:

Many new pharmacologic agents promoting angiostasis for the treatment of age-related macular degeneration are in development including anecortave acetate for depot suspension. Anecortave acetate is a slow-release depot suspension that may be delivered at 6-month intervals. This delivery allows for sustained delivery to the affected area near the macula when administered by posterior extrascleral placement. This procedure has not yet received final approval from the FDA. Additionally, there are currently no studies available on the long-term health outcomes of this procedure.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Covered. See Medicare Information.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
BlueCaid	Not covered

III. Administrative Guidelines: (BCNA, BCN65)

- The member's contract must be active at the time the service is rendered.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- Appropriate copayments will apply. Refer to certificate section, "Covered Benefits, Outpatient Services, Outpatient Surgery" and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.

IV. Effective Dates:

Policy updated: 7/1/09
 JUMP policy effective date: 5/1/08

Medical Policy update

- *The following applies to BCN members*
- *The effective date is indicated for the service, technology or procedure.*

Noncovered service

Conjunctival Incision with Posterior Extrasceral Placement of a Pharmacological Agent

- *Revised policy*
- *Effective date: 07/01/09*
- *Procedure code(s):*
 - **0124T – Conjunctival incision with posterior extrasceral placement of pharmacological agent (does not include supply of medication)*

Conjunctival incision with posterior extrasceral placement of a pharmacologic agent, e.g., anecortave acetate depot suspension, is experimental/investigational. This procedure has not yet received final approval from the Food and Drug Administration (FDA). There are no studies available on the long term health outcomes of this procedure. It has not been determined to be as safe and effective as currently available treatments.

Conjunctival incision with posterior extrasceral placement of a pharmacologic agent is covered for BCNA and BCN65 members based on Medicare guidelines.