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

Policy #: 254  
Category: Ophthalmology  
Latest Review Date: October 2009  
Policy Grade: **Effective October 1, 2009:** Active Policy  
but no longer scheduled for regular literature reviews and updates.

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Many new pharmacologic agents promoting angiostasis for the treatment of age-related macular degeneration are in development, including Anecortave Acetate (Retaane®) for Depot Suspension. Anecortave Acetate is a 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 six-month intervals and allows for sustained delivery to the affected area near the macula when administered by the novel procedure of posterior juxtascleral placement. Anecortave Acetate for Depot Suspension (Alcon Research, Ltd) received an approvable letter from the U.S. Food and Drug Administration (FDA) in May 2005 for treatment of age related macular degeneration but has not yet received final FDA approval.

In the conjunctival incision with posterior juxtascleral placement of the depot suspension procedure, after topical anesthesia, a 1.0-1.5 mm to 2-3 mm incision into the superior temporal quadrant of the orbit is made 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 not incise the sclera. A specially designed, blunt-tipped, curved, 56º cannula is then carefully inserted into the juxtascleral (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 removal of the cannula to prevent reflux and a semi-pressure patch is applied.

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).

**Policy:**
**Conjunctival incision with posterior juxtascleral placement of Anecortave Acetate Depot Suspension does not** meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational.**

*Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate 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.*
Key Points:
The procedure of conjunctival incision with posterior juxtascleral placement of 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 June 2003. Some patients in the study had this procedure performed several times in the same superior temporal 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 occurred at 27% and 30% and decreased visual acuity occurred at 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 included ptosis, ocular pain, vision abnormalities (e.g., hazy vision, black spots, light flashes, etc.), subconjunctival hemorrhage, and ocular pruritus. However, these events were reported as mild and transient in nature.

Anecortave Acetate has not yet received final FDA approval and further studies on long-term health outcomes are needed.

September 2007 Update
Anecortave acetate has not yet been FDA approved and the policy statement remains unchanged. Anecortave acetate is being evaluated in the Anecortave Acetate Risk Reduction Trial (AART) which began in 2004.

March 2009 Update
A Cochrane review of the Anecortave Acetate Clinical Study (AACS) concluded that, “anecortave acetate 15 mg may have a slight benefit in treating subfoveal CNV related to AMD. However, the data presented in the AACS are of low quality given the high attrition rate, inadequate sample size, lack of adjustment for multiple comparisons, and potential bias in the non-randomized re-treatment schedule.” The author’s (Geltzer, et al) overall conclusion was that “given the small size and quality of the trials reported, there is little evidence to support the use of steroids in the treatment of neovascular AMD.” Clinical studies of anecortave acetate are in progress for the treatment of other conditions. The available scientific evidence does not permit conclusions concerning the effect of this treatment on health outcomes. Therefore, the policy statement remains unchanged.

The FDA has advised in 2007 that approval of anecortave acetate (Retaane) would require an additional clinical study.

October 2009 Update
Per the July 2008 termination of studies, Alcon further elaborated that “the decision followed a planned interim analysis of studies C-02-60 A and B that was performed after 2,546 patients
had completed the 24 month time point. In this analysis, anecortave acetate showed no effect on the primary or secondary endpoints. In addition to terminating studies C-02-60 A and B, the company also terminated two smaller studies with an identical design that were being conducted in Asia, C-04-30 and C-05-34.”

In July 2009, Alcon officials also announced anecortave acetate would be withdrawn as a potential glaucoma therapy. While this application is not discussed previously in this policy, the announcement appears to indicate an end to development work on this agent. Alcon officials noted that “…the amount of IOP (intraocular pressure) reduction and the responder rate provided by even the highest dose were not sufficient to support this novel approach…”

No anecortave acetate depot products have been approved by the FDA as of September 2009.

**Key Words:**
Macular degeneration, Conjunctival incision, posterior juxtascleral placement of Anecortave Acetate Depot Suspension, Anecortave Acetate Depot Suspension, Retaane®, angiostatic cortisone

**Approved by Governing Bodies:**
Not FDA approved

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.
Pre-certification requirements: Not applicable

**Current Coding:**
CPT Codes:
- There are no specific CPT codes for this procedure *(Effective 01/01/2014)*

  68399 Unlisted procedure, conjunctiva

**Previous Coding:**
CPT Codes:
- 0124T Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication) *(Deleted 01/01/2014)*
References:

Policy History:
Medical Policy Group, October 2005 (2)
Medical Policy Administration Committee, October 2005
Available for comment October 24-December 7, 2005
Medical Policy Group, September 2006 (1)
Medical Policy Group, September 2007 (1)
Medical Policy Group, March 2009 (4)
Medical Policy Group, October 2009 (1): Active Policy but no longer scheduled for regular literature reviews and updates effective October 1, 2009
Medical Policy Group, December 2013 (1): 2014 Coding Update: added unlisted code 68399, effective for use 01/01/2014; moved deleted code 0124T to Previous Coding section, effective 01/01/2014

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.