APPENDIX to Suprachoroidal Delivery of Pharmacologic Agents Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

The structure of the eye is classified under two subheadings: (1) anterior segment, and (2) posterior segment. The anterior segment consists of the front one-third of the eye which includes; pupil, cornea, iris, ciliary body, aqueous humor, and lens; the posterior segment consists of the back two-thirds of the eye that includes vitreous humor, retina, choroid, macula, and optic nerve. Posterior segment ocular diseases (e.g., age-related macular degeneration, diabetic neuropathy) are the most prevalent causes of visual impairment. The following is a list of the various routes for ocular drug administration:

Invasive drug administration to intraocular cavities:

- Suprachoroidal injections
- Intravitreal surgery
- Intravitreal injections
- Intracameral surgery
- Subretinal injection
- Intracameral injections

Invasive periocular and scleral modes of drug administration:

- Intrascleral surgery
- Episcleral surgery
- Periocular injections
- Subconjuctival injections
- Transscleral diffusion from controlled release systems

Noninvasive methods:

- Topical administration

Systemic administration:

- Intravenous infusion and injection
- Oral

Topical application has remained the most preferred delivery route due to ease of administration. Topical application is useful in the treatment of disorders affecting the anterior segment of the eye. Although topical and systemic routes are convenient, lack of bioavailability and failure to deliver therapeutic levels of drugs to the retina has prompted vision scientists to continue to explore alternative routes of administration.

One potential advantage of suprachoroidal injection would be the ability to minimize systemic adverse effects while delivering higher local tissue levels of drugs. This proposed benefit assumes high local levels lead to improved outcomes. Weighed against this potential benefit is the risk of localized tissue damage from the microcannula. This technique is being investigated for the treatment of subchoroidal neovascularization related to diseases of the retina.

The iTrack™ (iScience Interventional, Menlo Park, CA), a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye for infusion and aspiration of fluids during surgery, received 510(k) marketing clearance from the United States Food and Drug Administration (FDA). The microcannula incorporates an optical fiber to allow transmission of light to the microcannula tip for surgical illumination and guidance. The microcannula "is indicated for fluid infusion and aspiration, as well as illumination, during surgery." (FDA, 2004).

A search of the MEDLINE database through December 2010 did not identify any clinical studies on the suprachoroidal delivery of pharmacologic agents. One review discussed tests of the suprachoroidal injection technique in pig eyes (Olsen, 2007). The industry-funded studies included pharmacokinetic analysis of triamcinolone (1% sodium hyaluronate in controls) in various tissues of the eye, as well as anatomic, physiologic, and short- and long-term histopathologic effects. Triamcinolone (3 milligrams) was found to remain at detectable levels in the posterior tissues of the pig eye for up to 120 days. Adverse events included infection (two of 94 pigs), scleral ectasia (four of 94 pigs), choroidal blood flow abnormalities (four of 94 pigs), and inflammation (six of 94 pigs). The author reported some cannula tip designs resulted in snag lesions in the pigment epithelium and the suprachoroidal space was found to separate from the sclera following injection of sodium hyaluronate but returned to a normal position after one month. The author noted that these data have been used to demonstrate the "relative" safety of

this methodology for humans and clinical trials are in progress to investigate the potential use of this technology for treatment of macular disease. This procedure is investigational.

A review article by Del Amo and Urtti (2008) discussed the emerging methods of ocular drug delivery, which include: polymeric-controlled release injections and implants; nanoparticulates; microencapsulated cells; iontophoresis; and gene therapy. The authors noted the biggest drug delivery challenge was to develop effective methods for posterior segment therapies that would also be applicable for outpatient use.

Evidence remains insufficient for the use of suprachoroidal delivery of pharmacologic agents to improve the net health outcome. Thus, this procedure is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	67299	Unlisted procedure, posterior segment *[when specified as suprachoroidal delivery of pharmacologic agent]*
HCPC	None	
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	

Type	Number	Description
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Epiretinal Radiation Therapy
- Photodynamic Therapy for Subfoveal Choroidal Neovascularization

Key / Related Searchable Words

- iTrack Microcatheter

References

- Blue Cross Blue Shield Association. Medical Policy Reference Manual, Policy No. 9.03.19 (October 2010).
- Del Amo EM, Urtti A. Current and future ophthalmic drug delivery systems. A shift to the posterior segment. Drug Discov Today 2008; 13(3-4):135-43.
- iScience Interventional. iTrackTM Microcatheter. iScience InterventionalTM. Menlo Park, CA. Retrieved January 23, 2011 from http://www.iscienceinterventional.com/US/itrack.htm.
- Olsen T. Drug delivery to the suprachoroidal space shows promise. Retina Today; March/April 2007. Retrieved January 24, 2011 from http://www.retinatoday.com/Html%20Pages/0307/0307_feature_olsen.pdf.
- United States Food and Drug Administration 510(k) Premarket Notification Database. iScience Surgical Ophthalmic Microcannula. Summary of Safety and Effectiveness. No. K041108. Rockville, MD: FDA. June 22, 2004. Retrieved January 20, 2011 from http://www.accessdata.fda.gov/cdrh_docs/pdf4/k041108.pdf.

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
4/1/2011	BCBSA Medical Policy adoption	Medical Policy Committee
5/2/2014	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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