

Corporate Medical Policy

Suprachoroidal Delivery of Pharmacologic Agents

File Name:	suprachoroidal_delivery_of_pharmacologic_agents
Origination:	2/2010
Last CAP Review:	6/2011
Next CAP Review:	6/2012
Last Review:	6/2011

Description of Procedure or Service

Delivery of pharmacologic agents to the suprachoroidal space is being investigated for treatment of posterior eye segment diseases.

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 that 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 injection

Invasive periocular and scleral modes of drug administration

- Intrasceral surgery
- Episcleral surgery
- Periocular injections
- Subconjunctival injections
- Transscleral diffusion from controlled release systems

Noninvasive methods

- Topical administration on the eye

Systemic administration

- Intravenous infusion and injection
- Oral

Many ocular diseases are treated with either topical or systemic medications. 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.

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One potential advantage of suprachoroidal injection would be the ability to minimize systemic side effects while delivering higher local tissue levels of drugs. This proposed benefit assumes that high local levels lead to improved outcomes. Weighed against this potential benefit is the risk of localized tissue damage from the microcannula. A microcannula system combines a drug delivery channel with a fiberoptic light source for localization of the cannula tip. This technique is being investigated for the treatment of subchoroidal neovascularization related to diseases of the retina.

The iTrack™ (iScience Interventional), which is 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 U.S. Food and Drug Administration (FDA). The FDA's 510(k) process usually does not require clinical trials to prove that the medical device is safe or effective. 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.”

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will not provide coverage for suprachoroidal delivery of a pharmacologic agent because it is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When suprachoroidal delivery of pharmacologic agents is covered

Not applicable.

When suprachoroidal delivery of pharmacologic agents is not covered

Suprachoroidal delivery of a pharmacologic agent is considered **investigational**. BCBSNC does not cover investigational services or procedures.

Policy Guidelines

At this time, there are no published, peer-reviewed studies available that address the safety and efficacy of suprachoroidal injection of a pharmacologic agent for treatment of any ophthalmologic condition. Clinical outcome studies are necessary to determine the value of this drug delivery method in the management of patients with diseases of the posterior segment of the eye and to determine whether this technique is superior to other currently available treatment options for posterior segment disease.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative

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Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0186T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.19, 10/6/09.

Senior Medical Director review - 1/2010.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.19, 10/8/2010.

Specialty Matched Consultant Advisory Panel Review - 6/2011.

Policy Implementation/Update Information

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| 2/2/2010 | New policy issued. Suprachoroidal delivery of a pharmacologic agent is considered investigational. (pmo) |
| 6/22/10 | Policy Number(s) removed (amw) |
| 7/19/11 | Specialty Matched Consultant Advisory Panel review 6/29/2011. Reference added. No change in policy statement. (lpr) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.