Suprachoroidal Delivery of Pharmacological Agents

Medical Policy

Section
Other

Original Policy Date
12/2013

Last Review Status/Date
Reviewed with literature review/12/2013

Issue
12/2013

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Description
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 injections

- Invasive periocular and scleral modes of drug administration
  - Intrascleral surgery
  - Episcleral surgery
  - Periocular injections
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. Though 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 for alternative routes of administration.

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 is used that 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.

**Regulatory Status**

The iTrack™ (iScience Interventional) 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 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."

**Related Policies**

9.03.08 Photodynamic Therapy for Subfoveal Choroidal Neovascularization
9.03.10 Thermal Laser Photocoagulation
9.03.20 Epiretinal Radiation for Age-Related Macular Degeneration

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**Policy**

Suprachoroidal delivery of a pharmacologic agent is considered **investigational**.
Beginning January 1, 2008, there is a category III CPT code specific to suprachoroidal delivery of pharmacologic agents:
0186T: Suprachoroidal delivery of pharmacologic agent (does not include supply of medication)

Rationale

At the time this policy was created, searches of the MEDLINE database 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. (1) 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 mg) was found to remain at detectable levels in the posterior tissues of the pig eye for up to 120 days. Adverse events included infection (2 of 94), scleral ectasia (4 of 94), choroidal blood flow abnormalities (4 of 94), and inflammation (6 of 94). The author reported that some cannula tip designs resulted in snag lesions in the pigment epithelium and that the suprachoroidal space was found to separate from the sclera following injection of sodium hyaluronate but returned to a normal position after 1 month. The author noted that these data have been used to demonstrate the “relative” safety of this methodology for humans and that clinical trials are in progress to investigate the potential use of this technology for treatment of macular disease.

A 2008 review article by Del Amo and Urtti discussed the emerging methods of ocular drug delivery, which include: polymeric-controlled release injections and implants; nanoparticulates; microencapsulated cells; iontophoresis; and gene therapy. (2) The authors note the biggest drug delivery challenge is to develop effective methods for posterior segment therapies that would also be applicable for outpatient use.

Periodic literature updates, the most recent performed for the period of September 2010 through July 2011, have identified a single prospective case series that used a microcatheter (iTRACK) for suprachoroidal drug delivery for the treatment of advanced, chronic macular edema with large subfoveal hard exudates in 6 eyes of 6 patients. (3) The subfoveal hard exudates were reported to be almost completely resolved at 1-2 months following a single suprachoroidal infusion of bevacizumab and triamcinolone, with no surgical or postoperative complications.

Summary

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

Medicare National Coverage

No national coverage determination

References:

1. Olsen T. Drug delivery to the suprachoroidal space shows promise. Retina Today; March/April 2007; available at:


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<td>Administration, physiological systems and anatomical regions, eye, percutaneous, code list for various agent types</td>
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Type of Service Vision
Place of Service Physician’s Office

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