Suprachoroidal Delivery of Pharmacologic Agents

Description

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

Background

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
  - Episceral surgery
  - Periocular injections
  - Subconjuctival injections
  - Transscleral diffusion from controlled release systems
- Noninvasive methods
  - Topical administration on the eye
• Systemic administration
  o Intravenous infusion and injection
  o 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.

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 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.

Regulatory Status

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 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.” (1)

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
9.03.24 Intravitreal Angiogenesis Inhibitors for Choroidal Vascular Conditions
9.03.26 Viscocanalostomy and Canaloplasty

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Suprachoroidal delivery of a pharmacologic agent is considered not medically necessary.
Searches of the MEDLINE database did not identify any clinical studies on the suprachoroidal delivery of pharmacologic agents. One 2007 review discussed industry-funded tests of the suprachoroidal injection technique in pig eyes. (2) 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). 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 1 month. Clinical trials in humans were reported to be ongoing.

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. (3) 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 have identified 2 small studies from the same group of investigators. One was a prospective case series (2012) 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. (4) 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.

In 2012, these investigators also published an industry-sponsored retrospective analysis of 21 eyes with choroidal neovascularization (CNV) secondary to age-related macular degeneration that were treated with bevacizumab and triamcinolone using the iTRACK microcatheter. (5) Patients were included in the analysis if they had been unresponsive to at least 3 prior treatments including thermal laser photocoagulation, photodynamic therapy, or intravitreal injections of pegaptanib, bevacizumab, or ranibizumab. Best corrected visual acuity (BCVA) did not improve significantly from baseline through the 6-month follow-up (0.98 logMAR at baseline, 0.92 logMAR at 1 month and 0.93 logMAR at 6 months). There was a significant decrease in central foveal thickness (407.2 microns at baseline to 333.3 microns at 1 month). There was no visible evidence of retinal or choroidal tissue trauma in this safety and feasibility study.

**Summary**

Controlled trials are needed to evaluate the safety and efficacy of suprachoroidal drug administration compared to the standard of care. Evidence to date consists of 2 small case series from the same group of investigators in Europe. Current evidence is insufficient to determine whether suprachoroidal delivery of pharmacologic agents improves the net health outcome. Thus, this procedure is considered **not medically necessary**.
Medicare National Coverage

There is no national coverage determination.

References


Policy History

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<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New Policy</td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; Policy statement unchanged.</td>
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Keywords

Suprachoroidal delivery
Choroidal neovascularization
Macular degeneration
iTrack

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 14, 2014 and is effective April 15, 2014.

Signature on File
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