BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Suprachoroidal Delivery of Pharmacological Agents

Policy #: 312
Category: Other

Latest Review Date: January 2021
Policy Grade: **Effective January 1, 2015: Active Policy but no longer scheduled for regular literature reviews and updates**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **suprachoroidal delivery of a pharmacologic agent** as a **non-covered** benefit and as **investigational**.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

DESCRIPTION OF PROCEDURE OR SERVICE:

Delivery of pharmacological agents to the suprachoroidal space is being investigated for treatment of diseases of the retina and optic nerve. A microcannula system is used that combines a drug delivery channel with a fiberoptic light source for localization of the cannula tip. 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. This technique is being investigated for the treatment of subchoroidal neovascularization related to diseases of the retina.

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

- 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.

An example of a device for suprachoroidal delivery of a pharmacologic agent includes the iTrack™ from iScience Interventional. All devices for suprachoroidal delivery of a pharmacologic agent are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

KEY POINTS:

Literature review through January 2021.

Summary of Evidence

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 two 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 investigational.

Practice Guidelines And Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Suprachoroidal delivery system, iTrack™, suprachoroidal delivery of pharmacological agents

APPROVED BY GOVERNING BODIES:

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."

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

67299	Unlisted procedure, posterior segment
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, January 2008
Available for comment January 9-February 22, 2008
Medical Policy Group, December 2008
Medical Policy Group, December 2009
Medical Policy Group, December 2010
Medical Policy Group, October 2011

Medical Policy Group, December 2013
Medical Policy Group, January 2014
Medical Policy Group, February 2015
Medical Policy Group, November 2019
Medical Policy Group, January 2021

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.