Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Suprachoroidal Delivery of Pharmacologic Agents

Description/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 and includes the pupil, cornea, iris, ciliary body, aqueous humor, and lens. The posterior segment consists of the back two-thirds of the eye that includes the vitreous humor, retina, choroid, macula, and optic nerve. Posterior segment ocular diseases (eg, age-related macular degeneration, macular edema, diabetic neuropathy, posterior uveitis, open-angle glaucoma,) are the most prevalent causes of visual impairment.

The most common route for ocular drug administration is by intravitreal injection. Other routes for drug delivery include topical, systemic, iontophoretic, juxtascleral and other injection routes. Extended-release intravitreal implants are relatively new delivery modes.

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 explore alternative routes of administration.

The suprachoroidal space is a potential space between the sclera and the choroid, and is a method to deliver therapeutics to the back of the eye. A potential advantage of suprachoroidal injection is the ability to minimize systemic adverse effects while delivering higher drug levels to local tissues. This proposed benefit assumes that high drug local levels lead to improved outcomes. Weighed against this potential benefit is the risk of localized tissue damage from 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 retinal diseases.

Uveitis

Uveitis is inflammation inside the eye. Inflammation usually happens when the immune system is fighting an infection. Sometimes uveitis means the immune system is fighting an eye infection but it can also happen when the immune system attacks healthy tissue in the eyes. Uveitis can cause problems like pain, redness, and vision loss. Uveitis damages the part of the eye called the uvea but it often affects other parts of the eye, too. Sometimes uveitis goes away quickly, but it can come back. Sometimes it's a chronic (long-term) condition. It can affect one eye or both eyes. Uveitis can cause vision loss if it isn't treated. Early uveitis symptoms usually start suddenly. Symptoms include blurry vision, floaters, eye pain, red eyes, and sensitivity to light. Uveitis can cause vision loss if you don't treat it.

Xipere

Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indication for the treatment of macular edema associated with uveitis. Additionally, Xipere comes packaged and supplied with one Suprachoridal Space (SCS) Microinjector® syringe with vial adapter attached, one 30-G x 900-µm needle, and one 30-G x 1100-µm needle (for administration in the back of the eye)[1].

Regulatory Status

The iTRACK™ formerly known as iScience (Ellex, Adelaide, South Australia), 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) in 2004. 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."[2] In a review of patented ocular drug delivery devices, Gilger, et al (2014) describe several suprachoroidal drug delivery devices and products (eg, sustained-release hydrogels and microparticles) in development.[3]

March 30, 2023 FDA approved iTrackTM Advance Canaloplasty Microcatheter with Advanced Delivery System[4]. The newest generation canaloplasty device for canal-based glaucoma surgery was available in May 2023 to surgeons in the U.S. to treat glaucoma. The iTrack microcatheter is the only product that is indicated for canal surgery to treat glaucoma with viscodilation alone. iTrack Advance is the latest addition to the iTrack family and is a high precision hand-held delivery system that places the clinically proven iTrack microcatheter into the main drainage canal of the eye for injection of viscoelastic fluid (canaloplasty) to clear blockages that cause elevated eye pressure (glaucoma). The original iTrack is principally used by glaucoma surgeons, whereas the new iTrack Advance, with the extended feature set, is expected to appeal to glaucoma surgeons as well as cataract surgeons and comprehensive surgeons, for use in a combination procedure alongside cataract surgery. iTrack Advance can be used by surgeons for both standalone procedures as well as in combination with cataract surgery.

Xipere was approved by the U.S. Food and Drug Administration (FDA) in October 2021 for the treatment of macular edema associated with uveitis. Xipere is administered as a suprachoroidal injection using the Suprachoridal Space (SCS) Microinjector®.[5]

The SCS Microinjector has not been approved by the FDA, only as part of the Xipere approval.[6]

Table 1. Human Trials of Suprachoroidal Therapies

Therapeutic Name(s)	Drug Class	Indication	Delivery Modality	Phase of Study	Clinical Trials Identifier
Triamcinolone acetonide, CLS-TA (Xipere)	Corticosteroid	Macular edema secondary to noninfectious uveitis	Microneedle	FDA approved	
Axitinib, CLX-AX	Tyrosine kinase inhibitor	Neovascular AMD	Microneedle	Phase 1/2a	NCT04626128
Belzupacap sarotalacan, AU-011	Viral nanoparticle	Primary indeterminate lesions and small choroidal melanoma	Microneedle	Phase 1	NCT04417530
RGX-314	AAV8 anti-VEGF Fab	Neovascular AMD, diabetic retinopathy	Microneedle	Phase 2	NCT04567550
Palucorcel, CNTO 2470	Human umbilical tissue derived cells	Geographic atrophy in AMD	Suprachoroidal cannulation	Phase 2	NCT02659098
GT005	AAV2-complement factor 1	Geographic atrophy in AMD	Suprachoroidal cannulation	Phase 2	NCT02286089
Human retinal pigment epithelium, Opregen	Human stem-cell derived retinal pigment epithelial cells	Geographic atrophy in AMD	Suprachoroidal cannulation	Phase 1/2a	NCT02286089

Medical Policy Statement

Suprachoroidal injection for the treatment of macular edema associated with uveitis is considered **established** when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:

The use of suprachoroidal injection of triamcinolone acetonide injectable suspension (Xipere®) is considered established for the following indications:

- Individual is 18 years of age of older, **and**
- Individual has diagnosis of macular edema associated with uveitis, **and**
- Individual does not have infectious uveitis, **and**
- Prescriber will not exceed the U.S. Food and Drug Administration (FDA) labeled dose of 4mg per affected eye

Exclusions:

- Suprachoroidal injection is not covered for all other indications.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

67516

Other codes (investigational, not medically necessary, etc.):

NA

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

One 2007, Olsen review discussed industry-funded tests of the suprachoroidal injection technique in pig eyes.[7] 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 after 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.[8] The authors note the biggest drug delivery challenge is to develop effective posterior segment therapies for use in the outpatient setting.

A prospective case series by Rizzo (2012) used a microcatheter (iTRACK™) for suprachoroidal drug delivery to treat advanced, chronic macular edema with large subfoveal hard exudates in 6 eyes of 6 patients.[9] Subfoveal hard exudates were reported to be almost completely resolved at 1 to 2 months after a single suprachoroidal infusion of bevacizumab and triamcinolone, with no surgical or postoperative complications.

In 2012, the investigators from the above mentioned Tetz study, published an industry-sponsored retrospective analysis of 21 eyes of 21 patients with choroidal neovascularization secondary to age-related macular degeneration treated with bevacizumab and triamcinolone using the iTRACK™ microcatheter.[10] 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 did not improve significantly from baseline through 6-month follow-up (baseline logMAR [minimum angle of resolution], 0.98; logMAR at 1 month, 0.92; logMAR at 6 months, 0.93; lower scores indicate improvement). There was a significant decrease in central foveal thickness (from 407 μm at baseline to 333 μm at 1 month). There was no visible evidence of retinal or choroidal tissue trauma in this safety and feasibility study.

Goldstein et al (2016) reported on a small, open-label, single-administration pilot study evaluating the safety, tolerability, and preliminary efficacy of suprachoroidal injection of triamcinolone acetonide in patients with non-infectious uveitis.[11] Nine individuals were enrolled in the study, five subjects with pan-uveitis, three subjects with anterior and intermediate uveitis, and one subject with intermediate uveitis. A single suprachoroidal injection of 4-mg triamcinolone acetonide in 100 µl was delivered in the study eye of patients. Observation occurred over 26 weeks. There were 38 reported adverse events; most were mild or moderate in severity. Approximately 50% the adverse events were ocular. The most common adverse event, ocular pain at or near the time of injection, was reported by 4 subjects. All systemic adverse events were unrelated to study drug. No steroid-related increases in intra-ocular pressure (IOP) were observed and no subject required IOP-lowering medication. All 8 efficacy-evaluable subjects had improvements in visual acuity; 4 subjects, who did not need additional therapy, had on average a greater than 2-line improvement in visual acuity through week 26; 3 of 4 had macular edema at baseline, and 2 of 3 had at least a 20% reduction in macular edema at week 26. The authors concluded that data from this study supports further research of suprachoroidally administered triamcinolone acetonide for the treatment of non-infectious uveitis. Ongoing and future controlled studies need to include masked centralized evaluations, larger study populations and repeated injections.

Willoughby et al (2018) conducted a prospective cohort study within a randomized, controlled phase 2 clinical trial, evaluating choroidal and suprachoroidal changes following suprachoroidal injection of triamcinolone acetonide injectable suspension (CLS-TA), in eyes with macular edema due to retinal vein occlusion.[12] Enhanced depth imaging optical coherence tomography images were analyzed from 38 eyes of 38 treatment-naïve patients

with macular edema due to retinal vein occlusion, enrolled in the prospective Suprachoroidal Injection of Triamcinolone Acetonide with Intravitreal Aflibercept in Subjects with Macular Edema Due to Retinal Vein Occlusion (TANZANITE) study who received either a suprachoroidal injection of CLS-TA with an intravitreal injection of aflibercept (combination arm) or only an intravitreal injection of aflibercept (monotherapy arm), followed by monthly intravitreal aflibercept injections in both arms based on pro re nata criteria. Macular choroidal thickness measured to the outer choroidal vessel lumen (vascular choroidal thickness), outer choroid stroma (stromal choroidal thickness), or inner scleral border (total choroidal thickness) showed no significant changes over 3 months in both study arms. Eyes that received combination therapy showed a trend toward thickening of the suprachoroidal space compared with monotherapy alone. In the 15 eyes that demonstrated a visible suprachoroidal space at baseline, the space expanded significantly after suprachoroidal CLS-TA injection. Based upon these study observations, suprachoroidal injection of CLS-TA does not appear to alter choroidal thickness in eyes with macular edema due to retinal vein occlusion; however, expansion of the suprachoroidal space may occur. Further studies are needed to draw definitive conclusions.

A review of the suprachoroidal space for drug delivery was published by Haim, et al (2021).[13] Clinical trials of suprachoroidal space injections of triamcinolone acetonide for various conditions and gene therapy developments in the clinical treatment of the posterior segment of the eye were discussed. The authors concluded that the suprachoroidal space is a promising route to administer drugs and advanced therapies to treat posterior segment diseases.

Lee (2018)[14] Clearside Biomedical announced that their proprietary formulation of triamcinolone acetonide (CLS-TA) improved vision in patients with macular edema associated with noninfectious uveitis. Injected into the suprachoroidal space using a single-use microinjector, the technique enables efficient delivery of triamcinolone to the posterior segment while limiting exposure to the anterior segment. The phase 3 PEACHTREE trial included 160 patients. Ninety-six were randomized to the treatment arm and received two 4.0 mg doses of suprachoroidal CLS-TA 12 weeks apart. The remaining 64 patients underwent sham procedures at the same 12-week interval. At the 24-week follow-up, 47% of CLS-TA patients gained at least 15 ETDRS letters, compared with 16% of controls ($P<0.001$). The study arm also showed significantly better mean improvements in BCVA (13.7 vs. 2.9 letters) and central subfield thickness (-157 vs. -19 microns) relative to controls.

The treatment was generally well tolerated and produced no serious adverse events. Through 24 weeks, corticosteroid-related elevated intraocular pressure adverse events were reported for approximately 11.5% of patients in the CLS-TA treatment group, compared with 0% of controls. “The PEACHTREE study was the first pivotal phase 3 clinical trial of a drug candidate for patients with uveitic macular edema in which a BCVA measure was the primary efficacy endpoint, potentially raising the bar for future trials in this population,” said investigator Rahul N. Khurana, MD, adding that suprachoroidal CLS-TA could potentially shift the treatment paradigm for these patients, pending additional positive results and FDA approval.
Habot-Wilner et al. (2019)[15] summarized that delivery of pharmaceuticals to the posterior segment presents challenges that arise from the anatomy and clearance pharmacokinetics of the eye. Systemic and several local administration options [topical, peri-ocular, IVT and sub-retinal] are in clinical use, each with a unique benefit-to-risk profile shaped by factors including the administered agent, frequency of dosing, achievable pharmaceutical concentrations within

posterior segment structures versus elsewhere in the eye or the body, invasiveness of the procedure and the inherent challenges with some administration methods. The use of the SCS, which is the region between the sclera and the choroid, is being explored as a potential approach to target pharmacotherapies to the posterior segment via a minimally invasive injection procedure. Pre-clinical data on agents such as vascular endothelial growth factor (VEGF) inhibitors and triamcinolone acetonide (TA) indicated that administration via suprachoroidal injection resulted in more posterior distribution of the pharmacologic agent, with higher exposure to the sclera, choroid, retinal pigment epithelium cells and retina, and lesser exposure to the anterior segment, than observed with IVT administration. Based in part on these findings, clinical trials have examined the safety and efficacy of suprachoroidal administration of pharmacologic therapies in conditions affecting the posterior segment. Data on a proprietary formulation of TA administered by suprachoroidal injection showed improvement in anatomic and visual outcomes in subjects with non-infectious uveitis, with the potential to mitigate the known risks of cataract and increased IOP associated with the use of intra-ocular corticosteroids. The authors concluded that suprachoroidal administration appeared to be a promising treatment modality and is also in the early stages of investigation for other possible applications, such as injection of anti-glaucoma agents into the anterior SCS for long-lasting control of elevated IOP, and as a mode of delivery for gene- or cell-based therapies for retinal disorders.

Price et al.(2020)[16] noted that macular edema (ME) is the most common cause of visual deterioration in non-infectious uveitis (NIU). The treatment of NIU with associated ME often includes locally or systemic administered corticosteroids, with long-term use limited by significant side effects. The need for a treatment with an improved safety profile has driven the development of a novel ophthalmic therapy: a proprietary triamcinolone acetonide suspension (CLS-TA) administered in the supra-choroidal (SC) space (XIPERE; Clearside Biomedical, Alpharetta, GA). Suprachoroidal delivery of corticosteroids allows higher steroid concentration in the posterior segment and decreases the risk of other ocular AEs. Recent results from the PEACHTREE study, a phase-III clinical trial with 2 SC injections of CLS-TA at 0 and 12 weeks with follow-up lasting 24 weeks, showed the significant improvement in VA and reduction in retinal central subfield thickness (CST), all without increasing the risk of elevated IOP or accelerated cataract progression.

Barakat (2021)[17] Summarized Drug delivery via the suprachoroidal space (SCS), with the potential to achieve chorioretinal concentrations 10 times greater than that of typical intravitreal injections, has shown safety and efficacy in the treatment of uveitic macular edema with a proprietary formulation of triamcinolone acetonide, CLS-TA. Administration of CLS-TA in the SCS, combined with afibercept, may also have the potential for reduced treatment burder over afibercept monotherapy in diabetic macular edema. Although early efforts exploring SCS injections focused on steroid delivery, a wide range of additional agents and indications are currently under development. (Tyrosine Kinase Inhibitors, Gene Therapy: Vector-Based, Gene Therapy: DNA Nanoparticles, Viral-Like Particle Bioconjugates). In conclusion, injection via the SCS has the potential to maximize treatment effect and minimize exposure of other ocular tissues. SCS injection of CLS-TA has shown efficacy in the treatment of uveitic macular edema and the potential of addressing the treatment burden of DME. With strong continued interest in harnessing the benefits of SCS drug delivery, multiple agents, from TKIs, to vector-based and DNP-based gene therapy, to light-activated VPBs, are at different stages of development for a spectrum of indications.

Gallardo (2021)[18] In this retrospective analysis of a consecutive case series, we evaluated the efficacy of iTrack ab-interno canaloplasty in reducing IOP and medication dependence, both as a standalone procedure (iTrack-alone) and in combination with cataract surgery iTrack+phaco) in POAG patients. The study cohort included 60 eyes of 53 patients presenting with POAG who met inclusion and exclusion criteria and completed the preoperative visit. The study cohort consisted of patients from Hispanic (73.5%), black (5.5%), or white (21%) ethnicity, across the glaucoma stages of mild (38%), moderate (17%) and severe (38%). The average age was 73.6 ±9 years (range 52–91). Patients had an overall mean preoperative IOP of 20.7±4.9 mmHg across all eyes on 2.77±0.9 medications (n=60). Comprehensive MIGS procedure that can be performed as a standalone procedure or combined with cataract surgery, and in cases of mild, moderate and severe glaucoma, iTrack ab-interno canaloplasty has a highly versatile potential. The 24-month follow-up data presented here show that it can be used effectively and safely to lower both IOP and the number of antiglaucoma medications. Thus, inclusion of iTrack ab-interno canaloplasty in the glaucoma treatment algorithm can help reduce or eliminate the need for antiglaucoma medications and delay more aggressive surgeries without limiting the use of future interventions. Relatively small group of patients confirm the need for prospective, multicenter trials with a larger patient cohort.

Kininska and Rekas (2023)[19] The surgical technique of suprachoroidal delivery via microcatheter requires a certain amount of dexterity and familiarity with microcatheter. The suprachoroidal space (SCS) is a potential space between sclera and choroid, which means that under normal conditions it is collapsed due to the IOP and fiber connections between both layers. It is only 35 µm thick, but it allows for a slight movement of choroid against sclera on accomodation. It is also a natural outflow pathway for aqueous humor, which is used in glaucoma surgery. Both Cypass and iStent are drainage devices placed in the SCS via an ab-interno approach. Any procedure performed in this area has a risk of rupturing the choroid and causing a suprachoroidal hemorrhage – a sight-threatening condition that requires prompt action. Upon injection, the SCS expands and collects fluid at one site. With the use of the microcatheter, it can be slowly distributed in a more diffused way, so that the volume does not extend the SCS excessively. What is more, the iTrack is equipped with an illuminated beacon tip that facilitates transscleral guidance, which is not possible in transscleral injections even with the help of a special injector. However, the triamcinolone acetonide for suprachoroidal injection has been approved safe by the FDA (with no cases of suprachoroidal hemorrhage in the trial) and is already commercially available. Both procedures require a setting of operating room and an experienced surgeon and both carry a risk of suprachoroidal hemorrhage. Other complications described with both methods in humans, i.e. IOP elevation, conjunctival hemorrhage, cataract, or uveitis, are manageable.

Summary of Evidence
Controlled clinical trials have shown the safety and efficacy of suprachoroidal drug administration. Current evidence is sufficient to determine whether suprachoroidal delivery of pharmacologic agents improves net health outcomes.

The evidence is sufficient to support the use of suprachoroidal injection of triamcinolone acetonide injectable suspension (Xipere) for the (FDA) approved indication for patients with macular edema associated with uveitis. The evidence is sufficient to support the use of

suprachoroidal injection for the (FDA) approved indication for individuals with macular edema associated with uveitis.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Clinical Trials
Current trials that may impact this policy are listed in Table 2.

Table 2. Summary of Clinical Trials

NCT number	Trial Name	Planned Enrollment	Completion Date
Recruiting			
NCT04417530	Phase 2 Trial to Evaluated Safety and Efficacy of AU-011 Via Suprachoroidal Administration in Subjects with Primary Indeterminate Lesions and Small Choroidal Melanoma (U.S.)	58	September 2024
Not Yet Recruiting			
NCT04690608	Suprachoroidal Injection of Triamcinolone Acetonide in Resistant Diabetic Macular Edema and CRVO (Resistant) (Egypt)	100	December 2021
Completed			
NCT02255032	Suprachoroidal Injection of Triamcinolone Acetonide in Subjects with Macular Edema Following Non-infectious Uveitis (DOGWOOD)	22	January 2016
NCT02303184	Suprachoroidal Injection of Triamcinolone Acetonide with IVT Aflibercept in Subjects with Macular Edema Following RVO (TANZANITE)	46	March 2016
NCT03097315	Suprachoroidal Injection of CLS-TA in Subjects Non-Infectious Uveitis (AZALEA) (U.S.)	38	January 2018
NCT02595398	Suprachoroidal Injection of CLS-TA in Subjects with Macular Edema Associated with Non-infectious Uveitis (PEACHTREE)	160	January 2018
NCT02952001	MAGNOLIA: Extension Study of Patients with Non-infectious Uveitis who Participated in CLS1001-301	33	May 2018
NCT03126786	Suprachoroidal CLS-TA with Intravitreal Aflibercept versus Aflibercept Alone in Subject with Diabetic Macular Edema (TYBEE)	71	April 2018
NCT01789320	Safety Study of Suprachoroidal Triamcinolone Acetonide via Microneedles to Treat Uveitis	11	March 2015
NCT02949024	Suprachoroidal Injection of CLS-TA Alone or with Aflibercept in Subjects with Diabetic Macular Edema (HULK)	20	October 2017
NCT05038072	The Use of Suprachoroidal Triamcinolone Acetonide to Treat Macular Edema in Retinal Vein Occlusion	16	February 2021
NCT05031143	Suprachoroidal Triamcinolone Acetonide in Harada's Retinal Detachment	6	August 2021
NCT04763369	Investigation of Therapeutic Efficacy and Safety of UMSCs for the Management of Retinitis Pigmentosa (RP)	50	June 2022
NCT05131646	Extension Study to Evaluate the Long-term Outcomes of Subjects in the CLS-AX CLS1002-101 Study	10	August 2022
NCT05099094	VEGFA-targeting Gene Therapy to Treat Retinal and Choroidal Neovascularization Diseases	18	September 2023
NCT04514653	RGX-314 Gene Therapy Administered in the Suprachoroidal Space for Participants with Neovascular Age-Related Macular Degeneration (nAMD)	95	January 2023

NCT04567550	RGX-314 Gene Therapy Administered in the Suprachoroidal Space for Participants with Diabetic Retinopathy (DR) Without Center Involved-Diabetic Macular Degeneration (CI-DME)	60	January 2023
Active, Not Recruiting			
NCT04626128	Safety and Tolerability Study of Suprachoroidal Injection of CLS-AX Following Anti-VEGF Therapy in Neovascular AMD (OASIS)	15	May 2022
Unknown			
NCT04069780	Suprachoroidal Injection of Triamcinolone Acetonide for Management of Diabetic Macular Edema (SCI) (Egypt)	45	Unknown
NCT03606733	Suprachoroidal Infection of Triamcinolone Acetonide Using Custom Made Needle to Treat Retinal Disorders	100	September 2019
Terminated			
NCT03203447	Suprachoroidal Injection of Triamcinolone Acetonide with IVT Anti-VEGF in Subjects with Macular Edema Following RVO	325	December 2018
NCT02980874	Suprachoroidal Injection of Triamcinolone Acetonide with IVT Aflibercept in Subjects with Macular Edema Following RVO	460	December 2018

NCT: national clinical trial

Government Regulations
National:

There is no national coverage determination on this topic.

Local

Wisconsin Physicians Service Insurance Corporation
Local Coverage Article: Billing and Coding: Category III Codes (A56902)
Original Effective Date 08/29/2019
Revision Effective Date 08/29/24

67516 is not listed as a covered category III procedure code.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Photodynamic Therapy for Choroidal Neovascularization
Aqueous Shunts and Stents for Glaucoma

References

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13. Haim NB and Moisseiev L. Drug delivery via the suprachoroidal space for the treatment of retinal diseases. Pharmaceutics. 2021: June: 13, 967
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19. Aleksandra K. Kicińska & Marek Rękas (2023) Alternative application of an iTrack microcatheter and canaloplasty: case report and literature review, Expert Opinion on Drug Delivery, 20:9, 1201-1208, DOI: 10.1080/17425247.2023.2256657

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/9/25, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/08	5/19/08	7/1/08	Joint policy established
7/1/09	4/21/09	5/11/09	Routine maintenance
3/1/12	12/13/11	12/21/11	Routine maintenance
5/1/14	2/24/14	3/3/14	Routine maintenance Code update: Deleted CPT code 0183T; added unlisted procedure code 67299.
5/1/16	2/16/16	2/16/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance Added procedure code 0465T; removed unlisted procedure code.
5/1/18	2/20/18	2/20/18	Routine maintenance
5/1/19	2/19/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance
5/1/21	2/16/21		Routine maintenance
5/1/22	2/15/22		Routine maintenance
5/1/23	2/21/23		Routine maintenance (jf) Vendor Managed: NA
5/1/24	2/20/24		Routine maintenance (jf) Vendor Managed: NA 2024 CPT Code Update added 67516 as EST and removed code 0465T as E/I. Edits to Description, Rationale, MPS and inclusions and exclusions. Added Ref: 1,4,5,14,15,16,17,18,19
5/1/25	2/18/25		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 1st Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SUPRACHOROIDAL DELIVERY OF PHARMACOLOGIC AGENTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.