Medica (formerly WellFirst Health)

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

☒ **Commercial (Small & Large Group)** ☒ **ASO** ☒ **Exchange/ACA**
☒ **Medicare Advantage (MAPD)**

RETISERT (fluocinolone acetonide intravitreal implant) MB2215

Covered Service: NO

Prior Authorization Required: NO

Additional Information: Prescribed by (or in consultation with) Ophthalmologist specialists with prior authorization through The Plan Pharmacy Services.

Medicare Policy: Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

Wisconsin Medicaid Policy Coverage of prescription drug benefits is administered by the Wisconsin Medicaid program. Coverage of medical drug benefits is administered by the Wisconsin Medicaid fee-for-service program. Medical drugs not paid on a fee-for-service basis by the Wisconsin Medicaid program are covered by the plan with no PA required.

1.0 FDA Indication

1.1 RETISERT (fluocinolone acetonide intravitreal implant) was approved by the U.S. Food and Drug Administration a corticosteroid indicated for the treatment of chronic noninfectious uveitis.

1.2 Background:

1.2.1 The iScience Surgical Ophthalmic Microcannula, or iTrack (iScience Surgical Corporation, Menlo Park, CA) is designed to access ocular structures such as schlemm's canal, subretinal space, vitreous cavity, and the suprachoroidal space. The iTrack received 510(k) clearance from the U.S. Food and Drug Administration on June 22, 2004 as a

flexible microcannual for atraumatic cannulation of spaces in the eye such as the anterior chamber and posterior segment, for infusion and aspiration of fluids during surgery, including saline and viscoelastics. The microcannula incorporates an optical fiber to allow transmission of light to the microcannula tip for surgical illumination and guidance.

1.2.1.1 Current drug delivery techniques to access the posterior segment of the eye include intra-vitreal injections, peri-ocular injections (i.e., subconjunctival, subtenon, or juxtascleral), and intra-vitreal implants. Drug delivery by injection into the suprachoroidal space is another technique that has recently been proposed in the treatment of posterior segment disease. The suprachoroidal space provides a potential route of access from the anterior region of the eye to the posterior region.

1.2.1.2 Suprachoroidal delivery of a pharmacologic agent is considered not having sufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure. There is inadequate evidence regarding the clinical utility of supracoroidal injection of pharmacologic agents for the treatment of any ophthalmologic condition. Clinical outcome studies published in the peer-reviewed medical literature are needed to determine the value of this drug delivery method in the management of patients with diseases of the posterior segment of the eye.

2.0 Policy / Criteria:

2.1 RETISERT (fluocinolone acetonide intravitreal implant) is considered not covered due to insufficient evidence to demonstrate clinical efficacy for treatment of chronic noninfectious uveitis.

2.1.1 True clinical benefit has not been established based the following:

2.1.1.1 Suprachoroidal delivery of a pharmacologic agent is considered not having sufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure

2.1.1.2 No societal or national guidelines

2.1.1.3 The delivery system has created increased risk of cataracts and increased IOP

3.0 Policy Rationale

3.1 Clinical data on suprachoroidal delivery of pharmacologic agents is lacking evidence of being superior to other delivery systems.

3.1.1 One 2007 review discussed industry funded tests of the suprachoroidal injection technique in pig eyes. (3) 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.

3.1.2 A 2008 review 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.(4) 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.

3.1.3 Periodic literature has 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. (5) The subfoveal hard exudates were reported to be almost completely resolved at 1 to 2 months following a single suprachoroidal infusion of bevacizumab and triamcinolone, with no surgical or postoperative complications.

3.1.4 In 2012, these investigators also published an industry-sponsored retrospective analysis of 21 eyes of 21 patients with choroidal neovascularization secondary to age-related macular degeneration that were treated with bevacizumab and triamcinolone using the iTRACK microcatheter.(6) 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 the 6-month follow-up (0.98 logMAR [minimum angle of resolution] at baseline, 0.92 logMAR at 1 month and 0.93 logMAR at 6 months; lower scores indicate improvement). There was a significant decrease in central foveal thickness (from 407.µm at baseline to 33µm at 1 month. There was no visible evidence of

3.2 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 investigational.

Comment(s):

1.0 *Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

1.1 NDC and HCPCS codes

***Suprachoroidal delivery of pharmacologic agents* :**	
CPT codes not covered for indications listed in the CPB:	
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)
0699T	Injection, posterior chamber of eye, medication
HCPCS codes not covered for indications listed in the CPB:	
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (e.g., intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed
Triamcinolone acetonide injectable suspension [Xipere]:	
CPT codes covered if selection criteria are met:	
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)
HCPCS codes if selection criteria are met:	
***Triamcinolone acetonide injectable suspension [Xipere]* – no specific code**	
ICD-hyphen10 codes covered if selection criteria are met:	
H35.81	Retinal edema
H44.131 – H44.139	Sympathetic uveitis

Medication Name		How Supplied	National Drug Code (NDC)	HCPCS code
Brand	Generic			
RETISERT	fluocinolone acetonide	0.59/ml	24208-0416-01	J7311

	intravitreal implant			

	Committee/Source	Date(s)
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