BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 11/26/13
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AQUEOUS SHUNTS AND STENTS FOR THE TREATMENT OF GLAUCOMA

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts, are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Micro-stents are also being investigated in individuals with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

AQUEOUS SHUNTS AND STENTS FOR THE TREATMENT OF GLAUCOMA (cont.)

Criteria:

- Insertion of FDA-approved aqueous shunts is considered ***medically necessary*** to reduce intraocular pressure for an individual with glaucoma when medical treatments have failed to adequately control intraocular pressure.

- Insertion of aqueous shunts for all other indications not previously listed or if above criteria not met, is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- Implantation of a single FDA-approved micro-stent in conjunction with cataract surgery in an individual with moderate open-angle glaucoma is considered ***medically necessary***.

- Implantation of a micro-stent for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

AQUEOUS SHUNTS AND STENTS FOR THE TREATMENT OF GLAUCOMA (cont.)

Resources:

Resources prior to 11/26/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 9.03.21 BCBS Association Medical Policy Reference Manual. Aqueous Shunts and Stents for Glaucoma. Re-issue date 09/12/2013, issue date 07/10/2008.

FDA 510K Summary Statements for Implant, eye valve (aqueous shunts). Device names include, *but are not limited to*:

Ahmed™ (New World Medical)
Baerveldt® (Abbott Medical Optics)
Express™ Mini Glaucoma Shunt (Alco)
Krupin (Eagle Vision)
Molteno® (Molteno Ophthalmic)

- FDA-approved indication: For the management of intractable glaucoma to reduce intraocular pressure where medical and conventional surgical treatments have failed.

FDA Premarket Approval Database for Aquaflow™ Collagen Glaucoma Drainage Device:

- FDA-approved indication: For the maintenance of a sub-scleral space following non-penetrating deep sclerectomy used to facilitate aqueous outflow for the reduction of intraocular pressure in patients with open angle glaucoma where intraocular pressure remains uncontrolled while on maximally tolerated medical therapy.

FDA Premarket Approval Database for Glaukos iStent® Trabecular Micro-Bypass Stent System:

- FDA-approved indication: For use in conjunction with cataract surgery for the reduction of intraocular pressure (iop) in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

AQUEOUS SHUNTS AND STENTS FOR THE TREATMENT OF GLAUCOMA (cont.)

Resources: (cont.)

FDA Premarket Approval Database for Glaukos iStent trabecular micro-bypass stent:

- FDA-approved indication: For use in conjunction with cataract surgery for the reduction of intraocular pressure (iop) in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.