Suprachoroidal Delivery of Pharmacological Agents

Effective: May 1, 2017

Next Review: March 2018
Last Review: March 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Suprachoroidal delivery of pharmacological agents is a method of drug delivery to the posterior eye segment, which is difficult to access. The agents are delivered via a flexible microcannula system that combines a drug delivery channel with a fiber optic illuminating tip that provides surgical guidance.

MEDICAL POLICY CRITERIA

Suprachoroidal delivery of pharmacologic agents is considered investigative for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Currently, 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.

REGULATORY STATUS

The iTrack™ device (iScience Interventional, Inc.) 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) clearance from the U.S. Food and Drug Administration (FDA).[1]

EVIDENCE SUMMARY

In order to determine the safety and effectiveness of suprachoroidal delivery of pharmacologic agents for treatment of posterior segment disorders, well-designed randomized controlled trials (RCTs) that compare this therapy to standard local drug delivery are needed. Further, for chronic conditions such as some posterior segment disorders, RCTs with long-term follow-up are necessary in order to determine the durability of any beneficial treatment effects.

Several nonrandomized studies have been published on the use of suprachoroidal drug delivery for various posterior segment eye disorders.[2,3] However, the results of these studies should be interpreted with caution due to the following limitations:

- Results from small sample sizes (n<100), limit the ability to rule out the role of chance as an explanation of study findings.[2,3]
- Evidence from case series is considered unreliable due to inherent methodological limitations, including but not limited to lack of adequate comparison group, without which it is not possible to account for the many types of bias that can affect study outcomes.[2,3]

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that address the use of suprachoroidal drug delivery for drug delivery in the treatment of any indication.

SUMMARY

There is not enough evidence to know if or how well suprachoroidal drug delivery of pharmacologic agents improves overall health outcomes in people who need treatment of posterior segment disorders or any other condition. In addition, no clinical practice guidelines address the use of suprachoroidal drug delivery to the eye for any indication. Therefore, suprachoroidal drug delivery is considered investigational for all indications.

REFERENCES

1. U.S. Food and Drug Administration (FDA) Medical Devices. iScience Surgical Ophthalmic Microcannula. [cited 03/03/2014]; Available from:

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