KAISER PERMANENTE®

Review Criteria

Georgia Region

DEPARTMENT:	Quality Resource Management	CRITERIA NUMBER:	No.01-29
SECTION:	Utilization Management	EFFECTIVE DATE:	2/8/2005
TITLE:	INTACS IMPLANTS	LAST REVISION DATE:	3/14/2024
		NEXT REVISION DATE:	3/14/2025
CRITERIA TYPE:	Reviewed/Revised	PAGE NUMBER:	1-5
APPROVAL BODY/ COMMITTEE:	Utilization Management Committee		

1.0 PURPOSE

This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

2.0 DIAGNOSIS/CONDITION

2.1 KERATOCONUS: ICD-10 codes: H18.609; Q13.4; H18.619

3.0 CPT/HCPCS CODES AND DESCRIPTIONS

3.1 CPT/HCPCS Code: 65785

4.0 INDICATIONS

4.1 INTACS for patients with keratoconus:

4.1.1 Have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles;

4.1.2 Are 21 years of age or older;

4.1.3 Have clear central corneas;

4.1.4 Have a corneal thickness of 450 microns or greater at the proposed incision site;

4.1.5 Corneal transplantation is the only remaining option to improve functional vision.

4.1.6 Patient has become intolerant to contact lenses and an attempt at refitting does not resolve the problem. * (see expert opinion Dr. Cameron Johnson TSPMG Opthalmogist under references).

5.0 CONTRAINDICATIONS

5.1 N/A

6.0 VIEW OF THE SOUTHEAST PERMANENTE MEDICAL GROUP

6.1 TSPMG supports the use of INTACS as an alternative to Corneal Transplant according to the FDA guidelines of 2004. Expert opinion from SCPMG also supports use of INTACS in order to avoid corneal transplant.

6.2 Expert Opinion from TSPMG Ophalmology- Dr. Cameron Johnson “Contact lens fitting can be difficult in patients with KC, requiring frequent visits and lens changes but recent advances in the contact lens industry has provided more fitting options. When good vision can no longer be attained with contact lenses or intolerance to the contact lens develops, corneal transplantation is recommended. "

6.3 Often after intacs, the cornea is regular enough that the patient can now tolerate a hard contact whereas they couldn't prior to INTACS.

7.0 CLINICAL SUMMARY

7.1 Keratoconus is a non-inflammatory, self-limiting ectasia of the axial portion of the cornea. It is characterized by progressive thinning and steepening of the central cornea. As the cornea steepens and thins, the patient experiences a decrease in vision which can be mild or severe depending on the amount of corneal tissue affected.

7.2 Keratoconus has no known cure, and many people do not even know they have it because it begins as nearsightedness and astigmatism. It is a progressive disorder that may progress rapidly or sometimes take years to develop. It can severely affect vision and function, including simple tasks such as driving, watching TV, or just reading a book. Some keratoconus patients have described their vision as being “blind with light.”

7.3 Treatment of keratoconus depends on the severity of the condition. Initially, eyeglasses are often successful in correcting the myopia (near sightedness) and astigmatism; however, as the disease advances vision is not adequately corrected and requires rigid contact lenses to aid in flattening the corneal surface and providing optimal visual correction. Contact lens fitting can be difficult in patients with KC, requiring frequent visits and lens changes but recent advances in the contact lens industry has provided more fitting options. Lastly, when good vision can no longer be attained with contact lenses or intolerance to the contact lens develops, corneal transplantation is recommended. This is only necessary in about 10% of patients with KC and carries a success rate of greater than 90%, one of the highest for corneal transplantation. Although this procedure replaces the thinned central portion of the corneal, eyeglasses and contact lenses are often required for maximal visual acuity.

8.0 **Reviews:**

8.1 Overview of the Technology

8.1.1 Intacs inserts are clear, thin prescription inserts placed in the periphery of the cornea by an ophthalmologist during a brief outpatient procedure. Intacs inserts reshape the curvature of the cornea from within, enhancing the natural shape of your eye to correct mild nearsightedness. Because no tissue is removed, natural optics are enhanced and the structural integrity of the cornea is maintained. Intacs inserts cannot be felt, are no more visible than a contact lens and require no maintenance. With Intacs inserts, many people are actually seeing better than 20/201. Intacs inserts are FDA approved and are supported by more than ten years of clinical studies.

8.1.2 Source: http://www.getintacs.com/us/patients/whatareintacs.htm

8.2 The FDA approved INTACS Prescription Inserts for Keratoconus in July 2004:

8.2.1 This device is indicated for the reduction or elimination of myopia and astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacles.

8.2.2 INTACS allow for a restoration of functional vision and potentially defers the need for a corneal transplant.

8.3 Aetna: 11/2020 Corneal Remodelling -Intrastromal corneal ring segments (INTACS).

8.3.1 Intrastromal corneal ring segments are considered medically necessary for reduction or elimination of myopia or astigmatism in persons with keratoconus or pellucid marginal degeneration who are no longer able to achieve adequate vision using contact lenses or spectacles and for whom corneal transplant is the only remaining option, in persons with a clear central cornea and corneal thickness of 450 microns or greater at the proposed incision site

8.3.2 Criteria agreed to by Dr Steve Hamilton, Eye Consultants

8.4 Expert opinion: Dr. Cameron Johnson TSPMG Ophthalmologist March 2014

8.4.1 “I have had patients in the past who, as their cornea becomes more irregular, cannot tolerate the contact more than a few minutes at a time due to pain from them. This does not allow them to have functional vision.”

8.4.2 "Contact lens fitting can be difficult in patients with KC, requiring frequent visits and lens changes but recent advances in the contact lens industry has provided more fitting options. Lastly, when good vision can no longer be attained with contact lenses or intolerance to the contact lens develops, corneal transplantation is recommended. "

8.4.3 Often after intacs, the cornea is regular enough that the patient can now tolerate a hard contact whereas they couldn't prior to INTACS

9.0 REFERENCES

9.1 UptoDate: Keratoconus December 2020

9.1.1 Intrastromal corneal ring segments were approved by the US Food and Drug Administration (FDA) in 2004 for the management of keratoconus. This technique has also been studied in combination with collagen cross-linking [24]. These thin, semicircular plastic inserts are implanted into the mid-corneal layers to flatten the cornea. The goal is to improve the patient's visual acuity by reducing the amount of astigmatism. Several authors have reported flattening of the cornea and significant improvement of refractive errors [25,26]. However, this treatment is not useful in patients with more advanced vision loss.

9.2 Corneal ring segments (INTACS) for the treatment of asymmetrical astigmatism of the keratoconus. Follow-up after 2 years

9.2.1 Tunc Z, Deveci N, Sener B, Bahcecioglu H. J Fr Ophtalmol. 2003 Oct;26(8):824-30CONCLUSION: We have observed that the flattening effect of INTACS inserts on the soft corneal keratoconic tissue and on the high astigmatic tissue seems greater than that produced in normal cornea. Implantation of INTACS resulted in a significant reduction in asymmetrical astigmatism of the keratoconus. PMID: 14586224 [PubMed - indexed for MEDLINE]

9.3 Intacs for keratoconus.

9.3.1 Boxer Wachler BS, Christie JP, Chandra NS, Chou B, Korn T, Nepomuceno R. Ophthalmology. 2003 May;110(5):1031-40.

9.3.2 Boxer Wachler Vision Institute, Beverly Hills, CA 90210, USA. CONCLUSIONS: Asymmetric Intacs implantation can improve both uncorrected and best spectacle-corrected visual acuity and can reduce irregular astigmatism in corneas with and without corneal scarring. PMID: 12750109 [PubMed - indexed for MEDLINE]

9.4 Management of keratoconus with Intacs.

9.4.1 Siganos CS, Kymionis GD, Kartakis N, Theodorakis MA, Astyrakakis N, Pallikaris IG. Am J Ophthalmol. 2003 Jan;135(1):64-70.

9.4.2 Department of Ophthalmology, the Vardinoyannion Eye Institute of Crete, University of Crete, Heraklion, Crete, Greece. csiganos@med.uoc.gr CONCLUSIONS: With mean follow-up of 11.3 months, intracorneal ring segments implantation improved UCVA and BCVA in the majority of the keratoconus patients. Even though the results are encouraging, concern still exists regarding the predictability as well as the long-term effect of such an approach for the management of keratoconus.

9.5 INTACS inserts for treating keratoconus: one-year results.

9.5.1 Colin J, Cochener B, Savary G, Malet F, Holmes-Higgin D. Ophthalmology. 2001 Aug;108(8):1409-14. Bordeaux University Hospital, Hopital Pellegrin, Bordeaux, France. CONCLUSIONS: INTACS micro-thin prescription inserts seem to provide a viable method for treating clear corneal keratoconus for

patients who are contact lens intolerant. The corneal steepening and astigmatism associated with keratoconus were reduced, and visual acuity was improved with treatment in almost all eyes.

Reviewed By/Approved By

The QRM Review Criteria Table of Content, which is documented in the Clinical Library under the "Utilization" tab, maintains a record of the document reviewers and approvers.

Kaiser Foundation Health Plan of Georgia developed internal coverage criteria based on current evidence from widely used treatment guidelines and clinical literature, as fully established applicable coverage criteria are not currently available in Medicare statutes, regulations, NCDs, or LCDs. This coverage criteria policy is publicly accessible.