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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intrasomal Corneal Ring Segments (INTACS Inserts)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Non-Covered Services (L35008).
Local Coverage Article	None
KPWA Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Intrasomal Corneal Ring Segments (INTACS Inserts)," for medical necessity determinations. Use the Non-Medicare criteria below.

Implantation of intrastromal corneal ring segments is identified as part of group 1, investigational, not proven effective or experimental. While use of this procedure has been largely for refractive and thus not medically necessary conditions, there is one notable exception. The FDA has approved use of these implantable devices for use in cases of the medical condition keratoconus, and other conditions where corneal thinning causes ectasia.

NAS agrees with the comment that 0099T is appropriate for use with keratoconus. Thus, 0099T will be removed from the non-covered policy. However, 0099T will continue to be not covered for refractive surgery which is not a Medicare benefit.

For Non-Medicare Members

1) Implantation of intrastromal corneal ring segments may be considered medically necessary for the treatment of keratoconus when **ALL of the following** criteria are met:
   - Functional vision cannot be achieved with contact lenses or spectacles
   - Age 21 years or older
   - Clear central cornea
   - Corneal transplantation is the only other remaining option to improve functional vision
2) Implantation of intrastromal corneal ring segments is considered not medically necessary for the treatment of myopia.
3) Implantation of intrastromal corneal ring segments is considered investigational for all other conditions including, but not limited to, pellucid marginal degeneration.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

Keratoconus is a progressive noninflammatory corneal disorder characterized by corneal thinning and protrusion of the central cornea. Signs and symptoms of keratoconus vary and depend on disease severity. In the early stages of keratoconus, individuals may be asymptomatic; however, as the disease progresses, there is considerable distortion of vision in the form of myopia and irregular astigmatism. For patients with mild to moderate keratoconus, vision may be corrected with spectacles or contact lenses. However, as the disorder progresses, or when the patients can no longer tolerate contact lenses, they are referred for corneal transplant (penetrating keratoplasty).The outcomes of this surgery are generally favorable; however, the surgery is not without complications. Complications of penetrating keratoplasty include graft rejection, intraocular damage, postoperative astigmatism, recurrence of keratoconus, and side effects from the long-term use of topical corticosteroids (Ambekar 2011, Ertan 2007, Romero-Jiménez 2010).

Intrasomal corneal ring segments (Intacs®) inserts are an alternative treatment strategy for patients with mild to moderate keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option. Intacs® inserts are small rings of synthetic material that are implanted in the deep corneal stroma with the aim of generating modifications of corneal curvature in an attempt to improve visual acuity, contact lens tolerance, and prevent or delay corneal transplant. The procedure is performed outside the corneal visual axis and the inserts may be removed or replaced if the desired outcome is not achieved. Intacs® inserts should not be used in patients who can achieve functional vision on a daily basis using contact lenses, are younger than 21 years of age, do not have clear corneas, or have corneal thickness less than 450 microns at the proposed incision site. Complications associated with Intacs® inserts include patient dissatisfaction with visual quality, discomfort, and ring segment extrusion or migration (Ambekar 2011, Bromley 2010, Ertan 2007, Romero-Jiménez 2010).

Intacs® inserts received FDA approval in 2004.

Medical Technology Assessment Committee (MTAC)

INTACS Inserts in the Treatment of Keratoconus

10/03/2005: MTAC REVIEW

Evidence Conclusion: The studies reviewed, as well as others revealed by the literature search, were all case series comparing the postoperative results to the preoperative values among the same groups of patients. Case series have potential selection and observation biases as well as other threats to internal validity. The results of these series may indicate some improvement in visual acuity after the implantation of Intacs in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to penetrating keratoplasty or other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (PK). In conclusion, larger studies with longer follow up and that compare the outcomes of the technology with those achieved with PK are needed to determine the efficacy and long-term stability, benefits, and harms of the technology.

Articles: The search revealed 18 articles. There were no meta-analyses or randomized controlled trials. All published studies identified were prospective or retrospective case series and had no control groups. Two prospective series on the use of Intacs for the management of keratoconus were selected for critical appraisal. Selection was based on the sample size, duration of follow-up, and quality of study. *Evidence tables were created for the following studies:* Hellstedt T, Makela J, Uusitalo R, et al. Treating keratoconus with Intacs corneal ring segments. *J Refract Surg.* 2005; 21:236-246. See Evidence Table. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. *AM J Opthalmol* 2003;135:64-70. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/19/2011: MTAC REVIEW

INTACS Inserts in the Treatment of Keratoconus

Evidence Conclusion: The study reviewed for the 2011 update, as well as those reviewed in the original 2005 MTAC review, were all case series comparing postoperative results to the preoperative values among the same groups of patients. Results from case series should be interpreted with caution as this type of study design is prone to bias. The results of these studies may indicate some improvement in visual acuity after the implantation of Intacs® inserts in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated

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with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (Colin 2007, Hellstedt 2005, Siganos 2003). Conclusion: There is insufficient evidence to determine the safety and efficacy of Intacs® inserts for the treatment of keratoconus.

Articles: The literature search did not reveal any meta-analyses or randomized controlled trials. The published studies identified were prospective or retrospective case series. The largest prospective case series with the longest duration of follow-up was selected for review.

The following study was critically appraised: Colin J and Malet F. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg. 2007;*33:69-74. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Date Created	Dates Reviewed	Date Last Revised
10/03/2005	Reinstated criteria on 01/03/2012 MDCRPC , 12/04/2012 MDCRPC ,10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015 MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC	01/03/2012

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
09/18/2015	Revised LCD L35008
12/05/2017	Adopted KPWA Policy for Medicare

Codes

CPT: 65785

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