CGS
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Multi-Jurisdictional Contractor Advisory Committee (CAC) Meeting

Key Questions

Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach

Table Quality of Evidence Grades	
Grade	**Definition**
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Copied from the GRADE Manual at https://gdt.gradepro.org/app/handbook/handbook.html

Using the GRADE format as a guide, please consider the following questions.

Effectiveness

1. What is considered the standard in which treatment would be considered effective for glaucoma management?[1-3] In other words, what would be the optimal primary end point for studies investigating glaucoma treatments?
    a. How is progression of glaucoma measured? Are the methods of measurement and data interpretation reproduceable across practitioners? Are measurements precise enough to establish the degree to which a disease process is slowed?
    b. Does IOP reduction affect all patients the same? What is the percent success rate of lowering IOP to slow disease progression? What defines success? In what studies is this success rate demonstrated? Is there a way to determine which patients would or would not benefit from lowering IOP?
2. Based on the pivotal studies[4-7] do you consider the anterior segment intraocular nonbiodegradable drug-eluting system an effective management for lowering intraocular pressure for patients with mild to moderate open angle glaucoma? Ocular hypertension?
3. Is there evidence to guide selection of this device over other treatment options (listed below)? If there is no evidence, what factors would you consider in making this decision?
    a. Medication alone

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b. MIGS procedure
c. Extraocular therapeutic options including wearable ocular surface devices, punctal plug systems and subconjunctival injections
d. Other interocular platforms such as bimatoprost sustained-release[8]

4. Does the evidence demonstrate if there is a decrease in the risk of patients progressing to glaucoma (OHT) or worsening glaucoma? In other words, can we determine if this device reduces the chance of vision loss over time? If yes, what evidence do you consider supporting this and why?

Patient Selection

5. Based on the evidence, what patient criteria should be considered for use of travoprost intracameral implant? [4-7,9]
    a. Is there evidence to support use in mild-moderate OAG? What about severe OAG?
    b. Is there a range of IOP that would be appropriate to use this device for OHT and if so what range?
    c. What are the absolute contraindications for this technology?
    d. What are the relative contraindications for this technology?
    e. What patient criteria e.g. medication non-adherence, physical inability in using drops, etc. would you consider relevant in selecting patients for this device? What documentation should be required?
6. What do you consider the limitations and strength of the referenced papers which represent pivotal papers used for FDA clearance of the device? [4-7,9]
7. The pivotal studies demonstrate non-interiority of the travoprost intracameral implant as compared to timolol drops. Do you consider this sufficient evidence to recommend the implant as standard of care?
    a. If no, what criteria would you consider before recommending this device as an alternative to standard of care medical management?
    b. If yes, what evidence influences that recommendation?
8. Durysta Bimatoprost implant (dissolvable) is a sustained release medication for lowering IOP for glaucoma or OHT after insertion into the anterior chamber.[10] The FDA label approves this for single injection.
    a. How do you determine patient selection for this device?
    b. Does the evidence support effectiveness?[8,9,11,12]
    c. Is there any evidence to support use of this in combination with MIGs procedures or other glaucoma managements?[13]
    d. Is there any evidence to support repeat administration of this device?

Safety

9. Both the pivotal studies and real world data have demonstrated safety of the device in a short term setting ranging from 3 to 24 months.[4-7,14-16] Do you have concerns about the lack of long term data on effectiveness and safety?
    a. If yes, how do these concerns impact your decision-making in-patient selection and use of the device?
    b. If no, what provides you with reassurance?

Coding

10. What ICD-10 codes do you consider appropriate for billing of 0660T?

Voting Questions (see survey)

The FDA label for iDose® TR[17] (travoprost intracameral implant) states iDose® TR is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with

open-angle glaucoma (OAG) or ocular hypertension (OHT). The dosing section of the FDA label reads: "iDose TR should not be readministered to an eye that received a prior iDose TR." The device is indicated for use up to 24 months. Medicare data show increasing use of this device off-label.

Is there evidence to support any of these off-label uses? If yes, please rank the quality of supporting evidence as very low, low, moderate or high per GRADE table above?

a. Use of the device beyond 24 months?[15]
b. Use of the device at the time of cataract surgery?[14]
c. Use of the device in conjunction with a MIG surgery?
d. Use in patients with permanently implanted titanium stents?
e. Repeating the device implantation after 24 months?
    i. Does repeat implantation provide equivalent efficacy in IOP lowering compared with the first implantation, or is there evidence of diminishing benefit?
    ii. If the device implantation is repeated, would you remove the previous device? Why or why not? Is there risk with a removal of this sort?
    iii. Could the presence of multiple devices impact future glaucoma treatment, including more definitive surgical management? If there is no evidence to support, do you think this should be a limitation of use until further investigations and longer-term outcome data is obtained?
    iv. Are there published data on the cumulative risks of multiple implants (e.g., endothelial health, inflammatory events, device retention)?
f. Use following prior placement of a different intracameral implant (e.g., Durysta)?
g. Use in conjunction with an implant an another segment of the eye such as implant into the lacrimal canaliculus (e.g., CPT code 68841)?

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