# National Institute for Health and Care Excellence

## IP375/2 – Miniature lens system implantation for advanced age-related macular degeneration Consultation Comments table

**IPAC date: 7 July 2016**

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| 1 | Consultee 1<br>Professional organisation<br>Macular Society | General | We have no experience of patient experiences of these implants in the NHS. We have considerable concern about the way some of the lens systems are sold in the private sector and have had significant numbers of patients contacting our helpline for information and advice following unsatisfactory procedures. | Thank you for your comments.<br>NICE interventional procedures programme provides guidance on the efficacy and safety of interventional procedures with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce new procedures appropriately.Guidance is issued to the NHS in England, Wales, Scotland and Northern Ireland and is also adopted in the UK in the independent sector via memoranda of understanding between NICE and the Association of British Insurers and the Independent Healthcare Advisory Services, respectively. |

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| 2 | Consultee 1<br>Professional organisation<br>Macular Society | General | The main issue appears to be with patient selection, unrealistic expectations, poor follow up and very high costs. There are very few helpful data to guide patients and some lens systems have virtually none available. | Thank you for your comments.<br>Section 1.3 of the guidance states that patient selection is important- *'Patient selection should include detailed assessment to predict the patient's ability to cope with the changes in vision after the operation. Extensive visual rehabilitation after the procedure may be required'.*<br>Section 1.2 states that clinicians should *'Ensure that patients understand the need to adapt to having a lens system implanted into one eye; the risk of early complications; and the uncertainties about long-term efficacy and safety.*<br>Section 1.5 *encourages further research and publication on which patients may benefit and on safety and efficacy outcomes, particularly longer-term results.*<br>Cost-effectiveness is not part of the remit of the IP Programme. |

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| 3 | Consultee 1<br>Professional organisation<br>Macular Society | General | It appears that the higher magnification lenses are difficult for people to adjust to and so are unsuitable for most people with AMD. The lower magnification lenses may not provide any improvement in vision in people with later stage AMD especially if they have little cataract. Patients with less AMD and a lot of cataract may experience improvement in vision although it is not clear if this is more than they would have had with a standard cataract operation. | Thank you for your comments.<br>In section 6.4 the committee noted that *'some patients reported good improvement in quality of vision whereas others reported difficulty in coping with high magnification images and did not achieve a satisfactory improvement in vision'.* |
| 4 | Consultee 1<br>Professional organisation<br>Macular Society | General | For most patients there is the likelihood that AMD will continue to progress and so any visual improvement may be lost. | Thank you for your comments.<br>In section 1.1 the committee noted that *'there is currently insufficient long-term evidence on both efficacy and safety'* and in section 1.5 it states that *'NICE encourages further research and publication on which patients may benefit and on safety and efficacy, particularly longer-term results'*. |

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| 5 | Consultee 1<br>Professional organisation<br>Macular Society | 1 | We believe there may be potential in these lenses for some people but more research is needed to understand who can benefit. As such we concur with NICE's draft guidance. | Thank you for your comment.<br>The committee added about research on patient selection in 1.5 as follows:<br>*1.5 NICE encourages further research and publication on which patients may benefit and on safety and efficacy outcomes, particularly longer-term results.* |
| 6 | Consultee 2<br>Professional organisation<br>The Royal College of Ophthalmologists | 1 | The recommendations are reasonable and the College supports the recommendations of the specialist advisers, especially in relation to the comments relating to patient expectation management and careful selection of patients. | Thank you for your comments. |
| 7 | Consultee 3<br>Company | 1.1 | The definition of short term and long term needs clarifying. The IMT (By Dr. Isaac Lipschitz) has 60 month peer reviewed post-surgical published data which is referenced in this document. This is significantly more than any other device referred to in the recommendations and considered by many to be long term data. | Thank you for your comments.<br>IPAC usually avoids being specific on length of time or defining the terms 'short' and 'long' term.<br>Evidence in the overview from individual studies has been presented per device type (for IMT, IOL-VIP system and Lipshitz macular implant). In section 6.1 of the guidance the committee added a comment that *'the majority of the evidence comes from one device'*. |

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| 8 | Consultee 3<br>Company | 4 | Interventional Procedure overview link not working so not able to access this. | Thank you for your comments.<br>The overview provides more details about individual studies. The consultee has been sent the link to the overview. |
| 9 | Consultee 3<br>Company | 6.1 | We are pleased that the committee noted that there are separate different lens systems. It appears that only 2 devices are referenced in this document with the majority of the data (all excluding the case series of 13 eyes â€“ 10 patients and case series of 6 eyes) coming from the IMT data (217 case series). It is our view that the mixing of data is very confusing for the reader and provides a skewed picture with regards to safety and efficacy and incorrectly increases the perception of safety and efficacy of the non IMT products by association. Data needs to be provided per device type. The type and magnification capability between the IMT (single enclosed device) and other 2 x independent IOL treatments is significantly different and incomparable. It also needs to be noted that the IMT is an FDA approved product, - something which underscores the safety and efficacy data. | Thank you for your comments. The IP programme issues guidance on procedures rather than individual devices.<br>Evidence in the overview from individual studies has been presented per device type (for IMT, IOL-VIP system and Lipshitz macular implant). In section 6.1 of the guidance the committee added a comment that ‘the majority of the evidence comes from one device’.<br><br>We have also made it clear in the overview that the *Implantable Minitaure Telescope is US FDA approved for monocular implantation in the capsular bag in patients with bilateral central scotomas associated with end stage age related macular degeneration, and visually significant cataract.* |

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| 10 | Consultee 3<br>Company | N/A | I am responsible for the sales and business development of the IMT internationally. I am commenting not to gain an unfair commercial advantage but to stress that the differences between devices as well as quality of data is significant and I am not sure that this is plainly evident to the reader. | Thank you for your comments.<br><br>In section 6, the committee noted 2 comments which state that<br>– *6.1 The committee noted that there are several different lens systems available for this procedure, and that these vary in complexity. The majority of evidence comes from one device.*<br>– *6.2 The committee noted that the technology and the techniques used in this procedure are evolving.* |