National Institute for Health and Care Excellence

IP 1218 – Sphenopalatine ganglion stimulation for chronic cluster headache
Consultation Comments table

IPAC date: 12 March 2015

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1: Manufacturer	**4**	In Section 4.1 there are inaccuracies in the documented number of attacks that were successfully treated during acute stimulation. In the CH-1 RCT, as published by Schoenen etal, the reduction in pain at 15 minutes when treated with acute stimulation was 67.1% (127/190), not (65/190) as cited in the document.	**Thank you for your comment** The Consultee is correct. In relation to the proportion of patients who experienced a reduction in pain, the right percentage (67.1%) is reported; however, the wrong numerator (65) is stated. This has been corrected to 127.

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2	Consultee 1: Manufacturer	**4**	As detailed in the document long term efficacy is yet to be published in a peer reviews journal. A manuscript is currently being finalized by Jurgens et al, which will report on 18 month outcomes, and will hopefully be published in the coming months. During 2014 however, a number of posters relating to these data were presented at international conferences. We appreciate that NICE looks at peer reviewed publications but hope that these data provide some insight to the long term outcomes of SPGS; Lianez et al, EHMTIC (European Headache and Migraine Trust International Conference), September 2014. Presented longer term efficacy of SPGS in 33 patients. The duration of the implantation varied from 117 to 575 days (mean 365 days) and assessed over 5000 acute cluster headache attacks. The analysis showed 2/3 of the 5,132 cluster headache attacks evaluated during the long term follow up period were effectively treated with SPG stimulation therapy. Furthermore , of the 2/3 of cluster headaches that were effectively treated, 77% of treated attacks did not require the use of additional acute medication.	**Thank you for your comment** Conference abstracts are not normally considered adequate to support decisions on efficacy and are not selected for presentation in the overview, unless they contain important safety data. The Lainez study is only available as a conference poster which reports no major safety concerns. As a result, it would not be included in table 2 of the overview. IPAC may review the guidance upon publication of new evidence in peer reviewed journals.

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3	Consultee 1: Manufacturer	**4**	Jurgens et al, Schmerzcongress (German Headache Congress), October 2014. Presented the data on the acute response of Sphenopalatine Ganglion Stimulation on more than 5,000 acute cluster headache attacks in the Long Term Follow Study. Data from 20 patients included in the LTFU (mean duration enrolled 365 days, range 117 – 575 days) and a total of 5,132 attacks were analyzed (average 112 ±298 per patient, range 1-1293 attacks). 82% of these attacks were treated successfully. In addition, 86% of attacks classified as moderate or severe were treated successfully.	**Thank you for your comment** Conference abstracts are not normally considered adequate to support decisions on efficacy and are not selected for presentation in the overview, unless they contain important safety data. The Jurgens study is only available as a conference poster which reports no major safety concerns. As a result, it would not be included in table 2 of the overview. IPAC may review the guidance upon publication of new evidence in peer reviewed journals.
4	Consultee 1: Manufacturer	**4**	Jurgens et al, Schmerzcongress (German Headache Congress), October 2014 Presented the data of 24 patients who had completed 18 months of follow up with Sphenopalatine Ganglion Stimulation. The analysis showed that 67% of acute responders maintain the ability to effectively treat 90.5% of treated acute attacks. 65% of frequency responders maintained reduction in attack frequency through LTFU. 88.6% average cluster attack frequency reduction in sustained frequency responders. 66% of patients in the LFTU study are acute and/or frequency responders to SPG stimulation, this compares favourable to the initial RCT study CH-1 in which 68% of patients enrolled were acute/frequency responders.	**Thank you for your comment** Conference abstracts are not normally considered adequate to support decisions on efficacy and are not selected for presentation in the overview, unless they contain important safety data. The Jurgens study is only available as a conference poster which reports no major safety concerns. As a result, it would not be included in table 2 of the overview. IPAC may review the guidance upon publication of new evidence in peer reviewed journals.

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5	Consultee 1: Manufacturer	**5**	Hillerup et al, EHMTIC (European Headache and Migraine Trust International Conference), September 2014. Presented long term safety data on 98 patients enrolled into either the CH-1 RCT or Pathway R-1 Registry. The analysis showed that 2/3rd of all related adverse events resolve on average within 70 days. 67% of patients experience sensory disturbances within 30 days of the insertion procedure with an average resolution time of 100 days. The majority of ongoing AEs are mild (63%) and do not have any effect on patients' day to day activities. When needed an explantion can be done under local anesthesia as an outpatient procedure. Adverse events related to the ATI Neurostimulation System are not different from sequelae reported for other trans-oral procedures.	**Thank you for your comment** The Hillerup (2014) study is a conference poster that was not identified during literature searches. It reports notable safety outcomes and has therefore been added to table 2 of the overview.