

National Institute for Health and Care Excellence

IP1125 – Electrotherapy for the treatment of haemorrhoids

Consultation Comments table

IPAC date: Thursday 12th March 2015

Due to the large number of consultation comments received, the comments have been organised into the following categories:

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Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
Agree with recommendations				
1	Consultee 7 Manufacturer	1	<p>Training, clinical governance, audit and research are needed going forwards, which is what we have implemented at this stage already, with plans to expand this as we go forwards, as well as to report our findings to advance our understanding of the Ultroid treatment procedure.</p> <p>With more patients presenting for consideration of their HD symptoms including bleeding, prolapsing and pruritus ani, opportunities for other areas of health screening and advice will be increased, as I have found. Rectal polyps, anal tags, various rashes and tumours can all be potentially diagnosed and appropriate action taken much earlier on than might otherwise have occurred (for example, I have picked up 3 early prostate cancers, a rectal tumour and inflammatory bowel disease myself already, all referred for appropriate further investigation and treatment). Once more patients realise that there is a more comfortable and safer treatment for their HD available, they will be more inclined to present for advice. This is a great opportunity to educate them, give a proper assessment and diagnosis and start an investigative process that might have wider implications for their long-term well being in more ways than one.</p>	Thank you for your comment.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
Disagree with recommendations				
2	Consultee 8 British Society of Gastroenterology	1	With respect to efficacy of the procedure one must be noted that if 21% of the patients in one study (number 1) did not tolerate the procedure this has a clear impact on its efficacy at population level as opposed to efficacy in cases where the procedure was tolerated.	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance stated that <i>'During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure is often painful and may not be tolerated: anaesthesia may be needed for electrotherapy to be used at a level of current that is efficacious.'</i></p> <p>The Committee decided to revise this to: <i>'During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful and may not be tolerated: anaesthesia may be needed for electrotherapy to be used at a level of current that is efficacious.'</i></p> <p>Following a request received during resolution period, further changes have been made to section 1.2 of the guidance and section 1.2 now reads:</p>

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				<p><i>'During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments for lower grade haemorrhoids. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful and general or regional anaesthesia may be needed to deliver electrotherapy at higher levels of current.'</i></p>

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
3	Consultee 7 Manufacturer	1 and 6	<p>Ultroid remains an outpatient treatment requiring no preparation beforehand, no anaesthesia or sedation, no post treatment recovery period in the clinic, and patients do not experience intolerable pain. The direct current is "tuneable" so that patient journeys are relatively comfortable, and as significant pain is not a prerequisite for clinical benefit, it is managed with appropriate tuning via dialogue maintained between doctor and patient. There is no need for anaesthesia, but if the patient's pain threshold is low, a lower current is applied for a longer period for the required amount of energy to be delivered to achieve the desired treatment effect. Given the non-disruptive nature of Ultroid treatments and the extremely low risk of complications, our patients prefer a course of treatments to anaesthetised surgery.</p>	<p>Thank you for your comment.</p> <p>The Committee discussed the need for anaesthesia and the tolerance to pain and noted that the procedure is usually performed without anaesthesia on a repeated treatment basis when used at low power settings.</p> <p>The Committee decided to make the following changes in sections 1.2 and 6.1. Section 1.2 now states:</p> <p><i>'During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful and may not be tolerated: anaesthesia may be needed for electrotherapy to be used at a level of current that is efficacious.'</i></p> <p>Following a request received during resolution period, further changes have been made to section 1.2 of the guidance and section 1.2 now reads:</p>

				<p><i>'During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments for lower grade haemorrhoids. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful and general or regional anaesthesia may be needed to deliver electrotherapy at higher levels of current.'</i></p> <p>Section 6.1 now states: <i>'The Committee noted that electrotherapy for the treatment of haemorrhoids is intended to be used as an outpatient procedure without anaesthesia, and that patients treated by the low power settings often need repeat procedures.'</i></p>
4	Consultee 7 Manufacturer	1 and 6	<p>The only exception to the experience of pain is in patients with anal fissures, when the proctoscopy itself can be painful. Use of local anaesthetic ointment or gel beforehand can make this more comfortable, but would not be attempted if initial digital examination was not possible. It is interesting that in the group of the first 100 patients I treated, 12 had anal fissures. I was able to carry out a successful Ultroid procedure after application of local anaesthetic ointment, with subsequent improvement in both the HD as well as (unexpectedly) more rapid resolution of the associated fissures than one might have expected. (This observation was the subject of the second poster I presented in Barcelona, and is certainly worthy of further specific study in the future for managing fissures associated with internal HD.)</p>	<p>Thank you for your comment.</p> <p>Refer to comment 3.</p>

5	Consultee 10 Specialist Adviser	1.2	<p>Having read the document I would like to put forward a few comments.</p> <p>Supporting anecdotal evidence to part 1.2</p> <p>In relation to this point, patients who come to clinic have already tried all non surgical treatments such as creams etc, and want to try electrotherapy as there is no general anaesthetic or hospital admission required. The current is increased slowly as tolerated by the patient and further increments are as tolerated by the patient. All patients who have come to clinic in our experience have tolerated the recommended current rate for grade of haemorrhoid. Although occasionally patients describe some minor discomfort, this is never enough to have to stop the treatment.</p>	<p>Thank you for your comment.</p> <p>As mentioned above, section 1.2 of the guidance has been changed to:</p> <p><i>'During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments for lower grade haemorrhoids. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful and general or regional anaesthesia may be needed to deliver electrotherapy at higher levels of current.'</i></p>
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Comments on current treatment options

6	Consultee 7 Manufacturer	1, 3, 6 and SAQ	In the NICE Specialist Advice - Electrotherapy for the treatment of haemorrhoids (1125/1) committee meeting on 11th December 2014, one of the commentators ventured that the Ultroid treatment lies between banding and surgery. In fact it can be chosen in substitution for both of these types of treatment, as it has been shown to be effective for all 4 grades of haemorrhoids.	<p>Thank you for your comment.</p> <p>Before a procedure is considered by the Committee, NICE seeks the opinion of at least two Specialist Advisers who are nominated by relevant Specialist Societies. This specialist advice is normally provided in the format of a questionnaire response.</p> <p>The Committee considered the evidence available for all grades of haemorrhoids and noted that there was little evidence in regards to grade IV haemorrhoids.</p> <p>The Committee decided to add a section 6.2 to the guidance which states: <i>'The Committee noted that there was little evidence about the use of this procedure for grade IV haemorrhoids.'</i></p>
7	Consultee 8 British Society of Gastroenterology	4	Most of the studies used as evidence are of little relevance to current UK practice. The procedure is described as intended outpatient procedure. The current standard in the UK is rubber band ligation. Only one study (study number 3) which reports on 100 patients is relevant to the UK practice. In this study the electrotherapy took longer than rubber band ligation. In study number 1 the procedure was reported to take 10 minutes per each haemorrhoid treated which implies an average of 20 minutes if two pedicles are treated and it is unreasonable to expect that 3 pedicle could be treated in outpatient settings. This is in contrast to rubber band ligation which can treat 3 pedicles in under 5 minutes. Study number one also reports that 21% of patients did not tolerate this procedure when was intended as outpatient procedure using low setting of 16mA. In this respect this procedure is far inferior to rubber band ligation.	<p>Thank you for your comment.</p> <p>The committee discussed current UK practice in the treatment of haemorrhoids. In reviewing the evidence on procedures the IP programme does not assess the efficacy and safety of comparator interventions.</p>

Comment on the mechanism of action

8	Consultee 7 Manufacturer	3	<p>I wanted to point out some factual inaccuracies in the documents included as part of the public consultation process:</p> <p>1/ in section 3.2 of the consultation document, the addition of the word "chemically" before cauterised should be considered, as just putting cauterised implies that there is heat involved, which there is not.</p>	<p>Thank you for your comment.</p> <p>The Committee considered this comment and noted that the precise mechanism of action of electrotherapy is not known. Therefore, section 3.2 of the guidance has been changed.</p> <p>Section 3.2 of the guidance now states: <i>'With the patient in the left lateral position, a proctoscope is inserted into the anus to identify a haemorrhoid. A probe with metal contact points is then placed at the base of the haemorrhoid above the dentate line and a direct electric current is delivered. The electric current is controlled by a handpiece attached to the probe. The time for which the electric current is applied depends on the grade of the haemorrhoid and on the dose of direct current. The aim of the direct current application is to cause thrombosis of the feeding vessels and to cause the haemorrhoid to shrink. The precise mechanism of action is not known. More than one haemorrhoid may be treated at each session, depending on the need and tolerance of the patient.'</i></p>
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Details of the technique/device

9	Consultee 7 Manufacturer	3	<p>2/ in the same document at 3.3, I think it would be fair to state that Ultroid is the only direct current device currently available for widespread clinical use and this is an out patient treatment device. Historically a higher amplitude amperage device delivering up to 30mAmps of current for use under GA or SA was available and studied, but to our knowledge it is not currently available in production to use and, as my experience has shown, is not needed.</p>	<p>Thank you for your comment.</p> <p>The IP programme issues guidance on procedures rather than individual devices.</p> <p>The Committee considered this comment and decided to amend section 3.3 of the guidance to clarify that the approaches described were identified in the literature review.</p> <p>Section 3.3 of the guidance now states: <i>‘One approach uses a low amplitude direct electric current (between 8 mA and 16 mA) and is used in an outpatient setting. Another approach described in the literature uses a higher amplitude direct electric current (up to 30 mA) with the patient under general or spinal anaesthesia.’</i></p>
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Miscellaneous observations on efficacy

10	Consultee 7 Manufacturer	4	<p>I set up Ultroid UK Ltd with two partners and started treating patients with haemorrhoid disease (HD) in 2013 in Canterbury, having trained in the technique in Tampa, Florida, USA with the most experienced doctor in the world in the Ultroid procedure. I had been struck by the efficacy and safety of Ultroid from my own review of the literature, from direct contact with the FDA (who reported not a single complication relating to more than 100,000 procedures performed), as well as contact with the technology provider and manufacturing company in the USA. During visits to the USA, I was impressed by the straightforwardness of the Ultroid treatment process and saw the possibility that this treatment could be introduced into the UK as a much safer treatment for patients suffering from HD compared to treatments currently used. It remains the only treatment that is FDA-approved for all grades of HD (1-4).</p>	<p>Thank you for your comment.</p>
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11	Consultee 7 Manufacturer	4	<p>I asked why there were no recent clinical studies of Ultroid, and found that the answer lies in the history of Ultroid in the USA. The Ultroid technology was patented in the late 1980s, but then bought and shelved by a competing company, following which no treatments were carried out for 15 years. Mr [REDACTED], the current Chairman of the US company, bought the patent rights in 2004 and has spent the last 10 years improving the technology, obtaining regulatory approvals, arranging for manufacture, patenting the improvements and reintroducing Ultroid into the US market. They are now looking to expand the business in the USA and worldwide. Ultroid UK Ltd. is leading this expansion in the UK and Ireland.</p> <p>To date, more than 400 treatments have been undertaken in the UK by myself and the two other doctors currently carrying out Ultroid treatments (Mr [REDACTED], CRS in [REDACTED], and Dr [REDACTED], General Surgeon in [REDACTED], working in our [REDACTED] clinic). The patients have been carefully assessed and treated and pertinent data collected, so we have considerable local experience and data available to analyse to better understand Ultroid from various perspectives, including clinical governance and audit.</p>	Thank you for your comment.
12	Consultee 7 Manufacturer	4	<p>Continued from comment 1 above:</p> <p>Contrary to the speculations of one of the commentators, there is no problem in delivering Ultroid treatments to prolapsed haemorrhoids, as the treatment site is at the base of the haemorrhoid. The majority of the patients I treated had grades 2-3 disease. Those with grade 2 HD that had resolved did so in 1-3 treatments. Those with grade 3 HD cleared in 1-6 treatments, most in the first 3 treatment sessions. I have previously sent copies of the posters to you for inclusion in your file.</p>	<p>Thank you for your comment.</p> <p>The consultee refers to a non peer-reviewed study. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee, unless they contain important safety data.</p> <p>Refer to comment 6.</p>

13	Consultee 7 Manufacturer	4	<p>I envisage that Ultroid could become the treatment of choice for all grades of HD. Proactive treatment of lower grade HD, together with dietary advice, may prevent disease progression, providing significant benefits to patients in the longer term. Patients unable to undergo surgical intervention because of other health-related problems, or who are unwilling to take the risks associated with surgery, could be offered the alternative of Ultroid treatment. At the present time, such patients have no such option. Indeed, many, if not all of my patients have elected to have Ultroid treatment to avoid surgery. Clearly advice on lifestyle factors as well is important, and we always provide that. What Ultroid offers those patients with reduced Quality of Life (QoL) and who are unable, due to other medical reasons, to undergo a general anaesthetic procedure, is a choice to have a potentially effective treatment for their disease. This advances equality of opportunity for active intervention in this group of patients who, at this time, are not afforded any such choice. I have treated several patients in this situation including those with severe lung disease, severe stroke, being wheelchair bound for different reasons etc. and, as a consequence, improved their QoL by improving their HD symptoms for them, giving them one less thing to worry about.</p>	Thank you for your comment.
14	Consultee 7 Manufacturer	4	<p>In order to bring Ultroid to the attention of interested doctors, we set up stands at three conferences last year—the ASGBI in Harrogate, the Tripartite Colorectal Conference in Birmingham and the ESCP meeting in Barcelona. We talked at some length with more than 125 colorectal surgeons, proctologists and general surgeons.</p> <p>The principal concern expressed by the doctors was the time it takes to deliver Ultroid treatments and the fact that a course of treatments may be required, depending on the severity of the disease and other factors. When balanced against the lack of disruption to patients’s lives, the low levels of pain during and following treatment and the extremely low risk of complications, many patients will choose Ultroid as their preferred treatment for their HD.</p>	Thank you for your comment.
15	Consultee 8 British Society of Gastroenterology	4	<p>This procedure is likely to be more expensive, less cost effective than the current gold standard in UK which is rubber band ligation in outpatient settings. It will require investment and more specific training for nursing staff and surgeons than the rubber band ligation.</p>	<p>Thank you for your comment.</p> <p>IPAC evaluates safety and efficacy. Cost-effectiveness is not part of the remit of the IP Programme.</p>

16	Consultee 9 Private sector professional	4	<p>I work with Dr [REDACTED] as a clinic nurse. One of my duties is to assist with the Ultroid procedure.</p> <p>I believe Ultroid is by far a better alternative to any other procedure available currently. Patients are able to have an Ultroid treatment and walk out again within an hour to carry on with their everyday lives. Other procedures for haemorrhoids are surgical, very invasive and can be difficult to recover from resulting in potentially long hospital stays, time off work and considerable discomfort for the patient. Some patients do find the procedure a little more uncomfortable than others but the energy/current used during the treatment can be lowered and the time allowed for treatment of a given haemorrhoid just takes a little longer. Patients need no anaesthetic and there is no recovery time after the treatment. Some patients may need more than one treatment to get complete relief depending on the grade/severity of their haemorrhoid disease but this can potentially be booked at a time to fit in with the patients work/life commitments.</p>	Thank you for your comment.
17	Consultee 12 Private sector professional	4	<p>I have been the secretary for [REDACTED] for 6 months now and have worked with Dr [REDACTED] for the whole time that he has been involved with the Ultroid treatment for haemorrhoids. I did not at first quite understand how the treatment worked and was very skeptical whether it would or in fact could work. I have completely changed my mind on this and can with confidence and honesty say that it does work for the majority of patients who undergo the treatment. I have first hand experience of patients who have come in for follow up treatments telling me that they have had relief of symptoms since their last treatment. One in fact travelled the 12'ish hour round journey from up north just to tell Dr [REDACTED] how happy he was that he was symptom free for the first time in years and that he had been on a holiday where he had walked for several hours which he had not been able to do for many years. This patient had previously had banding, two HALO procedures and two haemorrhoidectomies, and still had plies! Many patients will come down from treatment and say they are feeling more comfortable already and they will often go off for a walk to see the sights of [REDACTED] straight after their treatment!</p>	Thank you for your comment.

Comment on the evidence available

18	Consultee 7 Manufacturer	4	I presented two posters to the European Society of Coloproctology (ESCP) in September in Barcelona, both of which have been published in abstract form in the journal, Colorectal Disease, Vol. 16, Supplement 3, September 2014. I gave an oral presentation to the meeting relating to the key poster (OP47, page 18), which summarised the results from the first 100 patients who received Ultroid treatments in the UK. I treated patients with all 4 grades of haemorrhoid disease (HD) and had resolved symptoms in the majority, with others still requiring further treatment(s) for complete disease control. It was of note that the patients with grade 1 HD all resolved after a single treatment. Specifically the two patients with grade 4 disease had completely resolved after a total of 6 treatments each, carried out at monthly intervals, demonstrating that Ultroid is both a safe as well as an effective alternative to surgery for grade 4 haemorrhoids. The retraction of these prolapsed haemorrhoids to eventually leave patients symptom free was impressive.	Thank you for your comment. Conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview, unless they contain important safety data.
19	Consultee 8 British Society of Gastroenterology	4	The level of evidence included is generally low with 2 of the studies included (study 8 from Iran with 931 cases) and study 9 from USA with 120 cases) being cases series with low level of evidence.	Thank you for your comment. The safety and efficacy outcomes reported are those which are described in the available evidence.
20	Consultee 8 British Society of Gastroenterology	4	There are no studies reported to compare this procedure done under general or regional anaesthesia at higher setting (more effective) with the hemorrhoidal artery ligation.	Thank you for your comment. The safety and efficacy outcomes reported are those which are described in the available evidence.

Miscellaneous observations on safety

21	Consultee 8 British Society of Gastroenterology	5.2	If 20% of the patients in one study did not tolerate the procedure this has a clear impact on its efficacy at population level as opposed to efficacy in cases where the procedure was tolerated. This makes it an unattractive option as extends treatment and consultation time by requiring a different procedure to be undertaken in the same setting or rescheduling to the patient.	Thank you for your comment. Refer to comment 2.
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Comments about SAQs

22	Consultee 7 Manufacturer	5	3/ the theoretical adverse events listed in section 5.7 include burning and electrocution. Both are highly unlikely from using the Ultroid device as it has two fuses and numerous other features built into the device to make it safe. The device delivers only 5.1V and a maximum of 16mA of direct current. More than 120,000 Ultroid treatments have taken place in the US and elsewhere without any such issues. TUV compliance and certification as well as CE marking of the equipment are in place. This TUV America test report certificate (No. U8 10 01 72186 001) is available (I have emailed to the team for your information).	Thank you for your comment. Section 5.7 is the opinion of the Specialist Advisers and will not be changed.
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Observations on committee comments

23	Consultee 7 Manufacturer	6	There is some confusion in discussions about Ultroid around the term ‘recurrence’. As noted, a single treatment is not sufficient in a significant number of cases: rather, a course of treatments is required. If, as is common for grade 3 and 4 haemorrhoids, several treatments are required, we would not say that there had been a ‘recurrence’ during the treatment course. Our patients have been prepared to undergo two or more treatments in preference to invasive treatments, which will be more disruptive to their lives. Once the course of Ultroid treatments has been completed and the HD resolved, our experience to date is that there is no recurrence of the haemorrhoids at these specific sites. It is of course possible that patients could develop haemorrhoids in other locations, and I have certainly seen this in some patients, but this is no different to any other technique used to treat HD. I have had one poor patient that had previously had two HALO procedures, two haemorrhoidectomies and still had HD! He had one treatment with Ultroid and his piles completely went, and have not recurred thus far a year on!	Thank you for your comment. The Committee has considered this comment and has noted that several procedures are often used to treat the haemorrhoids at the low power settings. Therefore, section 6.1 of the guidance has been changed. Section 6.1 of the guidance now states: <i>‘The Committee noted that electrotherapy for the treatment of haemorrhoids is intended to be used as an outpatient procedure without anaesthesia, and that patients treated by the low power settings often need repeat procedures.’</i>
24	Consultee 7 Manufacturer	6	4/ under 6.1 I would point out at there is no significant evidence that the lower amperage used to treat HD in more sensitive patients is associated with either lower response rates or higher recurrence rates.	Thank you for your comment. Refer to comment 23.

25	Consultee 10 Specialist Adviser	6.1	<p>Supporting anecdotal evidence to part 6.1</p> <p>Throughout the consultation process discussions with patients include the possibility of repeat treatments. In our experience this is not considered a negative, as the treatment remains in an out-patient setting with immediate return to work and no disruption to routine daily activities. Patients therefor consider it a worthwhile procedure. I also offer surgery as an option for those with grade 4 prolapsing haemorrhoids , but often patients are understandably extremely reluctant on a surgical solution for a variety of reasons, including significant anaesthetic risks due to co-morbidity.</p> <p>I hope these comments are useful.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 23.</p>
Demands for procedure to be available				
26	Consultee 4 Patient	4	<p>Private treatments are however, expensive, so the sooner this treatment is available on NHS the better . As far as I can tell, the treatment could be given in a GP practice .</p>	<p>Thank you for your comment.</p> <p>The Interventional Procedures programme at NICE assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.</p>
27	Consultee 5 Patient	4	<p>In the construction industry haemorrhoids are a common problem and I have come across lots of sufferers like myself and in the gym also, and I now recommend the Ultroid treatment to anyone I come across and the possibility of it being available on the NHS is probably is not a minute too soon. As I said I am most happy to tell my story as the treatment has made a great difference to my life and I couldn't speak any higher about it.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 26.</p>

28	Consultee 7 Manufacturer	4	We have had many enquiries from potential patients who cannot afford the cost of private treatment and would be delighted if Ultroid became available on the NHS. This was the prime reason I initially got involved as I saw "in theory" that Ultroid offered a better alternative than the other currently available treatments for this common and embarrassing condition. Having now had a lot of personal experience treating patients, I remain more firmly convinced that this is the way forward for many patients as the safest option for them with the least disruption to their lives. The fact that Ultroid could be carried out in any suitable clinic space in Primary Care facilities, in secondary care facilities or in private clinics makes this a treatment that could save valuable theatre time, with associated significant cost savings in the long term for the NHS. With the minimal risk of significant complications, there are further huge cost savings to make here as well.	Thank you for your comment. IPAC evaluates safety and efficacy. Cost-effectiveness is not part of the remit of the IP Programme.
29	Consultee 9 Private sector professional	1	Due to the straightforward nature of the treatment, I can foresee that this could be carried out in a primary care setting rather than in a hospital, bringing care closer to home for the patient and freeing up valuable theatre time for more pressing procedures in the hospital.	Thank you for your comment. Refer to comment 26.
30	Consultee 9 Private sector professional	5	The minimal risk of significant complications would also save a lot of precious bed days in hospital as well, thereby saving significant sums for the NHS in the medium to long term. I can foresee both trained GPs and Specialist Nurses being able to undertake Ultroid treatments rather than relying on Colorectal Surgical teams.	Thank you for your comment. Refer to comment 28.
31	Consultee 9 Private sector professional	1	I believe Ultroid should be offered as the treatment of choice for haemorrhoid disease due to the non surgical aspect and ability for patients to carry on with their everyday lives straight afterwards.	Thank you for your comment. Refer to comment 26.

32	Consultee 12 Private sector professional	1	<p>I truly do believe this would be a fantastic addition to the NHS treatments dealing with this debilitating condition before it gets to the point where peoples' lives are being affected so badly. Ultroid, as an outpatient treatment, would also save the NHS a lot of money. Not only by preventing higher grade disease with all that that holds, but also the cost involved with a full operation and all the equipment, staff and medication required for operative procedures. By avoiding the need for general anaesthesia, as much as the operation itself, the risks involved for patients are substantially reduced.</p> <p>We had one gentleman recently who is elderly and disabled, having had a fairly severe stroke, and who's son said had been too high a risk for an operation. He still suffered from significant haemorrhoids just as badly as an able-bodied person and he was able to have Ultroid treatment, giving him some relief from his symptoms and he was so pleased, as was his son, who was his carer. Most patients do not find the discomfort of treatment with Ultroid too bad at all. Indeed one female patient said she could have fallen asleep during it!</p>	<p>Thank you for your comment.</p> <p>Refer to comment 26.</p>
33	Consultee 12 Private sector professional	4	<p>All in all, Ultroid is really changing the lives of patients for the better. Most of our patients had been too scared to have the other treatments recommended for their piles by the doctors they had seen previously. When they heard about Ultroid, they were at long last pleased to find a treatment that could potentially solve their embarrassing problems with minimal risk and all as an outpatient.</p> <p>I really hope Ultroid will be available for everyone soon, as from my secretarial observers position, the great stories of improvement reported to me by our patients should be the sorts of stories that any patient should be able to tell, irrespective of their ability to pay for the treatment.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 26.</p>

Personal experience and notes

34	Consultee 1 Patient	4	I have had prolapse piles and after having this treatment the piles have almost receded with another treatment due they should have completely receded , a great treatment ,painless and able to carry one as normal after	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
35	Consultee 2 Patient	4	Having had problems for several years and have had an operation, which took some time to recover from, injections and banding (which can hurt depending on how much experience the dr has), previously I can honestly recommend electro therapy , slightly uncomfortable nothing more no recovery time needed and very beneficial I would highly recommend.	Thank you for your comment. Refer to comment 34.
36	Consultee 3 Patient	4	I had Electrotherapy (Ultroid) performed on my stage 3 haemorrhoids approx 12 months ago (Dec/Jan) I experienced some slight discomfort during the procedure. The result over the following week was that my haemorrhoids shrank back. However a couple of months later they started returning. I am now due for a course of follow up treatment.	Thank you for your comment. Refer to comment 34.
37	Consultee 4 Patient	4	I have been having treatment for a year using 'ultroid' . Currently I have had 5 treatments. The piles are significantly reduced, with 2 of the 3 , to all intents non existent and one remaining troublesome pile. The remaining pile is reduced in size and manageable, but I will continue treatment until it is no longer relevant ! The treatment itself is not particularly painful, and post treatment there is a healing period of up to two weeks which consists of some minor discomfort and some disruption of normal bowel movements. Assessment of the condition of the problems is really only possible after this period, and generally I wait at least a month before deciding on further treatments. Incidentally I train and walk to the appointment and home.....much better than hospital and surgery, which would have been the alternative - note I have had surgery approx. 20 years ago for the same problem ! Overall from a patient perspective, this is by far preferable to surgery, and appears to be very effective !	Thank you for your comment. Refer to comment 34.

38	Consultee 5 Patient	4	<p>I have been requested to add my testimonial regarding my haemorrhoids treatment by Ultroid.</p> <p>I'd like to start by giving you a little background, I first suffered with the problem when I was around 9 years old, this was only very sporadic for a short period of my childhood but when I first started working as a carpenter, because all of the heavy manual lifting involved the haemorrhoids returned with a vengeance.</p> <p>Firstly they were just uncomfortable and the occasional blood when going to the toilet and when at their worst, either over the counter cream or suppositories would clear the them up and the discomfort would go until the next episode.</p> <p>In my mid twenties I started lifting weights and bodybuilding in the gym, maybe unwisely in retrospect, both further lifting and straining in the gym and at work, this only increased the frequency of the haemorrhoid attacks, pain and bleeding, so much so that I used to take suppositories in my both my gym and work bag.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 34.</p>
39	Consultee 5 Patient	4	<p>In my thirties, I had moved away from manual labour at work into construction site management, and with family and work commitments the gym became only a infrequent hobby, but I was still plagued with the haemorrhoids ! Very painful frequently and bleeding sometimes quite profusely when I use the toilet, even bleeding without any reason during the day, which is both uncomfortable and very embarrassing, the worst incident of this was while at work on site in London, when sitting in the office on a hot day doing paperwork, I felt like I was sitting on a wet chair, when I stood up and checked, the whole back of my jeans seat and back of legs where drenched in blood and I had to send one of my site foremen to the shop to buy a new pair of jeans so I could travel home.</p> <p>As much as I have suffered with Haemorrhoids I have never bothered with going to the doctors since I was a child to do anything about them and I have just lived with them and used over the counter treatments, as to be frank the horror stories I had heard, and even a few people I know that I have witnessed the agony they are in after the treatments, made the me refuse to have any form of medical procedure.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 34.</p>

40	Consultee 5 Patient	4	<p>I phoned [REDACTED] and discussed things further with their representative Mr [REDACTED] and was further put at ease and cheered up, as he told me he had the treatment himself and had suffered the same problems I had during my life with Haemorrhoids. I booked for a consultation at their [REDACTED] Clinic.</p> <p>At my consultation I was told by the examiner that I had Two grade 3, internal haemorrhoids and one Grade 2 partially external (I can't recall the correct terminology). Again I booked myself in for the treatment straight away.</p> <p>I returned to the clinic in [REDACTED] the following week for my treatment and although still a little nervous at the procedure, I was put at ease the moment it started. The treatment was painless, a little uncomfortable at most, and personally I would say was more the discomfort of my haemorrhoids and not the process itself.</p> <p>I had one, ten minute session on the two grade 3's and 5 minutes on the grade 2, with a short break between, which I was very happy to take place as didn't really want any return visits. When the treatment was completed as I went to sit up I was expecting to feel some form of pain or discomfort but just felt fine.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 34.</p>
41	Consultee 5 Patient	4	<p>Over the next week or so the usual pain of the haemorrhoids vanished completely and have no issues with blood or discomfort when using the toilet.</p> <p>It has been about 18 months since I had the treatment with Ultroid UK and when asked if I would give a testimonial on my treatment, I was more than happy to do so and be able to say how very pleased with the treatment and that I am amazed after all the years of suffering and all the horror stories of the types of treatment, that I could walk into a clinic and after 30 minutes walk out again without any pain or discomfort, and now 18 months on I can use the gym without fear of embarrassment or the pain of haemorrhoids.</p>	<p>Thank you for your comment.</p> <p>Refer to comment 34.</p>

42	Consultee 6 Patient	4	I had a very good experience with Ultroid. After the treatment I have not experienced any bleeding when emptying my bowel and also have found my external hemorrhoids improved.	Thank you for your comment. Refer to comment 34.
43	Consultee 11 Patient	4	I believe that Ultroid treatment should be available to everyone on the NHS. I have had the treatment which is quick and not much pain. It has helped me enormously as I was in terrible pain and within a short period of time I was pain free.	Thank you for your comment. Refer to comment 34.
44	Consultee 1 Patient	NOTE	Should be widely available as it would save thousands of time and money .	Thank you for your comment. IPAC evaluates safety and efficacy. Cost-effectiveness is not part of the remit of the IP Programme.
45	Consultee 7 Manufacturer	NOTE	As the most experienced Ultroid practitioner in Europe, I would be more than happy to answer any questions anyone may wish to ask about Ultroid. If I do not know the answer and it is likely that the US company might have this information, I would be able to clarify with the manufacturers if needs be.	Thank you for your comment.
46	Consultee 8 British Society of Gastroenterology	NOTE	I and a Colorectal Surgeon and treat regularly haemorrhoidal disease in outpatient and inpatient setting. I am fully familiar with rubber band ligation, injection sclerotherapy , haemorrhoidal artery ligation, stapled haemorrhoidopexy, diathermy haemorrhoidectomy and ligasure haemorrhoidectomy. I am aware of Ultraloid device from industry advertising materials but have never used it. I submit these comments as designated expert from British Society of Gastroenterology.	Thank you for your comment.
47	Consultee 10 Specialist Adviser	NOTE	I do a haemorrhoid clinic, and offer ultroid treatment as 1 of many options available to treat patients with haemorrhoids	Thank you for your comment.
48	Consultee 7 Manufacturer	General	My name is Dr [REDACTED] and I would like to introduce myself to you as the Managing Director and Medical Director of [REDACTED]. I also continue to work privately as a Consultant Dermatologist and Dermatological and Laser Surgeon in [REDACTED] as well as being an Honorary Consultant Dermatologist for [REDACTED] Hospitals University NHS Foundation Trust.	Thank you for your comment.

49	Consultee 7 Manufacturer	General	As a key representative of Ultroid UK Ltd., I fully support the NICE assessment process and I sincerely hope my insight has been helpful in adding to the discussion of Electrotherapy for the Treatment of Haemorrhoids.	Thank you for your comment.
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"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."