Comments on the ACD Received from the Public through the NICE Website

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	No
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a patient suffering with chronic migraine, who has benefitted from three treatments of Botox injections, I consider that the Appraisal Committee should without doubt recommend botulinum toxin type A for the prevention of headaches in adults with chronic migraine. Â My response to the injections has been 'life changing'. Â Prior to the injections, I was suffering with typically 26-30 days of totally debilitating pain per month. Â This was reduced by more than 50% following the second administration of Botox. Â I have not been part of a trial of Botox but have been given this treatment by my consultant neurologist after having tried numerous other prophylactic drugs (and many alternative therapies) to no effect over a 20-year period. Â According to my consultant neurologist, not only has the frequency of my severe headache days reduced but my background headache severity has improved as assessed using the HIT6 score i.e. 66 to 64. Â There has also been a halving of my Hospital Depression score and reduction in my Hospital Anxiety score. Â He feels that this is largely related to the reduction in headache related impairment leading to resolution of reactive anxiety/depressive symptoms.
Section 2 (The technology)	I have experienced several significant benefits, the major one being the reduction of the frequency and severity of the pain - a reduction from almost constant pain to just a few days of pain a month. Â There has also been a lifting of the horrible cloud of depression which accompanies the pain and for the first time in many years, a return of a clear mind, enabling me to get on with my life and my work. Â The Botox injections help dramatically with all aspects of the condition including the head pain, depression, irritability, exhaustion, clumsiness, speech difficulties and cognitive impairment. Â Unlike some of the other medicines which I have used for my chronic migraine (e.g. Amitryptyline, Propranalol), I have suffered no side effects from treatment with Botox.
Section 3 (The manufacturer's submission)	Botox is the only treatment which has enabled me to live a normal life for the first time in twenty years. Â If this treatment is not made available on the NHS, I am not sure how I would be able to carry on. Â I have had to borrow the money to pay for the treatment on a private basis up to now from my elderly parents who are unable to continue to support this indefinitely. Â I would be suffering in utter misery just wanting to 'chop my head off'. Â If this treatment were available on the NHS, it would mean that I would be able to have the injections as required, leaving me without pain and able to get on with my life, do my work, be a proper father to my three children and generally make a contribution to society. Â The total cost of the treatment to the NHS would work out at Â£29.12 per

	week (based on your figures). Â To me this is a small price to pay to be able to live my life. Â I will be able to contribute many times this sum per week by being able to get on with my work, earn money and pay income tax instead of drawing Statutory Sick Pay and other benefits e.g. Child Tax Credit.
Section 4 (Consideration of the evidence)	The effect of the migraines drastically reduces my ability to get on with my work (and life in general). Â As I am self employed, this reduces my income significantly and reduces my ability to pay for the Botox injections privately. Â The cost to the NHS would be significantly outweighed by my increase in productivity and quality of life. Â For example I would not need to claim periods of Statutory Sick Pay, as I have had to do prior to the Botox treatment, and my earnings would be greater such that I would be paying more income tax and therefore making a worthwhile contribution to the UK economy rather than being a burden. Â I understand your necessity to consider all aspects of the introduction of such a treatment through the NHS but your whole document is based on a very theoretical approach. Â Hopefully my comments outlined above will bring some real evidence of the effectiveness of Botox in the prophylactic treatment of chronic migraine in adults from someone who has experienced this first hand!
Section 5 (Implementation)	
Section 6 (Related NICE guidance)	
Section 7 (Proposed date of review of guidance)	
Date	07/03/2012 @20:03

Name	[redacted]
Role	Patient
Location	Scotland
Conflict	No
Notes	I have recieved Botox for chronic migraine which significantly helped reduce the amount and severity of my migraines.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	How much does it cost for an person to stay in hospital for 5 days and recieve intravenous D.H.E. which dosnt work very well but is offered because everything else has been tried?
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I am sorry but I didnt really understand all of the report, but I would like to say I am a 48 yr old woman with chronic migraine who cannot hold down a job because of it. I have had progressivly worsening migraines since age 12 and have taken many medicines for the condition, both preventitives and pain relief, non of which have been effective. Approx a year ago I was given injections of Botox and had a wonderful 4 months of reduced migraines and deminished pain. Now I am back to dreadful pain almost everyday, constantly battling the desire to take frequent pain relief.Please, please make Botox available for those of us who need it. Thank you.
Section 5 (Implementation)	
Section 6 (Related NICE guidance)	
Section 7 (Proposed date of review of guidance)	
Date	07/03/2012 @16:03

Name	[redacted]
Role	NHS Professional
Other role	[redacted] National Migraine Centre, London EC1M 6DX
Location	England
Conflict	Yes
Notes	I was a triallist in the PREEMPT study heve lectured on migraine and Botox for Allergan, and have participated in advisory boads for Allergan. The National Migraine Center has received financial support from Allergan.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Stopping rules: there can be made to work in a robust and auditable manner using patient-held headache diaries, copied for the medical record. In clinic, no diary means no Botox treatment. Differential utilities: counting headache days captures useful information but does not tell the whole story. Many patients I have treated with prophylaxis, including Botox, advise that headache may have diminished duration or impact fewer associated symptoms e.g. vomiting or enhanced acute treatment response: taking, compared with not taking prophylaxis.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Related NICE guidance)	
Section 7 (Proposed date of review of guidance)	
Date	06/03/2012 @12:03

Name	[redacted]
Role	NHS Professional
Other role	Health Professional (private sector)
Location	England
Conflict	yes
Notes	I am [redacted] at the Walton Centre for Neurosciences, Liverpool, on a phase 4 safety trial for Boptox in chronic migraine. I have been paid to discuss botox at adboards and have received sponsorship from Allergan to attend major neurology and headache conferences.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a consultant neurologist and run a quarternary clinic in the UK for refractory and severe headache disorders. the neurology units in the North West UK agreed a protocol with commissioners regarding use of Botox and commissioners agreed to fund Botox in such cases. Despite this, I am aware that as a neurology Trust serving more than 3 million patients, we have actually considered and/or moved to treat patients with Botox in less than 10 cases as of this date. This includes many patients seen for some years in one of very few specific "refractory" headache clinics. As such, I believe that it is appropriate use of resources to treat the small number of patients who haev nothing else to offer, who have fully eliminated all medication and caffeine overuse, who have maintained excellent lifestyle re fluids/food/sleep, where we have eliminated and treated comorbid sleep disorder first and they have failed a minimum of at least 3 reasonable trials of preventative drug. This is as per the North West protocol. I state this, as I believe it is possible to prescribe and treat just those patients who have nothing else to offer and have very severe disability and distress.
Section 2 (The technology)	This treatment is a relatively safe one when comparede with other migraine preventatives. Just this week I have seen a patient with neutropenia from an anticonvulsant (prolonged admission after number of GP visits before diagnosed), a patient with heart block on calcium anatagonist, and a patient who has come off topiramate (only drug out of more than 9 preventatives to have worked) where she developed severe renal calculi on topiramate. I often see such problems and many of the drugs we use are extremely toxic, causing both severe morbidity (as above) or severe side effects (eg 1/4 of those on topirmaate for migraien develop severe cognitive disturbance, mood disorder, or suicidal ideation. In comparison, Botox has an excellent safety profile. In addition, with the North West Botox protocol, it is cost effective (patients do not get triptans etc to any degree)
Section 3 (The manufacturer's submission)	1. patients for botox should be those who have by definition failed other treatments. 2. they are very disabled. 3. if the North West protocol or similar is adopted, the process would select those most in need (a very very small number of all migraineurs) in the most difficult state, they would receiveonly 2 sessions and then be evaluated by established disability/impact scales and diary, and would only continue if 30% response at 6 months. If good response, they would receive Rx for 1 year only, then have 6-8 month assessment period with possibility of further Rx year

	thereafter. 4. Costs would need to be offset against cost of GP visits/A+E visits (often admitted as ? subarachnoid haemorrhage - to CT and LP etc to DGH), against costs of other acute treatment (triptans, painkillers, antiemetics) and against other preventatives (cost of Rx and dealing with severe side effects. Data from open label studies shows response of 2/3 reduction in headache days, with redued severity as average response. We should only continue to treat those that respond. If you want, I can send North West Protocol as agreed with commissioners in N West UK if is agreement from commissioners/Walton
Section 4 (Consideration of the evidence)	Allergan is conducting further studies and I am principal investigator in one. We have a catch 22 situation. NICE wants more information. The provisional report has led to Commissioners temporarily halting North West Protocol and our Trust treating new patients. The Allergan study does not pay for Botox. Hence I cant add new patients to study that will increase knowledge on Botox. I have already made comments regarding evidence. In the N West UK, we haev a protocol that allows us only to continue in those with clearly documented efficacy. In clinical practice, we always utilise a placebo response (friend of the physician, foe of the researcher!). In clinical practice we do not have an alternative (we can not "give" placebo as it is unique to a trial setting. The patients treated under an agreed protocol such as we use only continue if proven benefit and only start treatment after many leayers of other treatment (a. strict elimination of acute attack drugs and caffeine & exemplary lifestyle, b. failed Rx on Â 3 (often Â than3) preventative trials each Â 4 months @ max tolerated dose,c. Rx sleep disorder. Placebo response likley would have been seen before if "respond" to botox.
Section 5 (Implementation)	We have established a protocol in the North West UK that should be evaluated as a pilot in the UK (in my opinion) to determine if utility of Botox will provide effective treatment for low cost, maximising selection, retention and further evaluation criteria for patients to only continue to use Botox where proven long term benefit, stopped after reasonable treatment period and not maintained where poor response. And only given where failed number of other first line treatments, most likely where we have nothing else to offer this highly disabled group (WHO rank migraine as one of top 4 most disabling conditions, equal alongside dementia, psychosis and quadriplegia) - these patients usually have no alternative at this late stage of treatnment and nowhere else to turn - often young, lose jobs, families break up (I see this regularly in this group). Yet, Botox has proven benefit in some patients vs placebo. Guidance from NICE needs to take this into account
Section 6 (Related NICE guidance)	
Section 7 (Proposed date of review of guidance)	This is a long way away
Date	02/03/2012 @14:03