National Institute for Health and Clinical Excellence

622/2 – Deep dermal injection of non absorbable gel polymer for HIV-related facial lipoatrophy

Consultation Comments table

IPAC date: Thursday 8 November 2012

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS professional	General comment	I believe clinicians should only be allowed to recruit patients for such studies for trials which have been properly constructed and have ethical committee approval	Thank you for your comment.
2	Consultee 2 British HIV Association	Title in lay description section	**Treating HIV-related lipoatrophy by injecting a non-absorbable gel polymer** BHIVA response: "Specifically the earlier drugs used in treatment, which are rarely used now – failure to mention this may give the reader the impression that this is still a not uncommon problem with newer HIV agents (which it is not)."	Thank you for your comment. The Committee amended section 2.1.1 to mention this point (see response for comment 6).
3	Consultee 2 British HIV Association	1.1	**Current evidence on the efficacy of deep dermal injection of non-absorbable gel polymer (NAGP) for HIV-related facial lipoatrophy is adequate.** BHIVA response: "BHIVA would argue that it is 'limited' and restricted to single centre reports using differing NAGP's, different procedures, and rarely comparing treatment methods. Data on comparisons of NAGP's is rare and there is limited evidence of longterm efficacy and safety."	Thank you for your comment. The Committee considered the evidence presented to be adequate to make a recommendation about special arrangements. Section 1.4 encourages further research and data collection.

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4	Consultee 2 British HIV Association	1.1	**Therefore, this procedure should be performed only with special arrangements for clinical governance, consent and audit or research.** BHIVA response: “Ordinarily, this would only be performed by plastic surgeons with the appropriate specialty certification.	Thank you for your comment. The guidance does include the recommendation at section 1.3 that ‘clinicians using this procedure should be trained in the technique of injecting non-absorbable gel polymers’. IP guidance does not usually specify any particular certification.
5	Consultee 3 Clinician		Most concern with this product revolves around safety and the strong anecdotal evidence, particularly from plastic surgeons, around complications which develop months to years after treatment. Such long-term data is difficult to capture.	Thank you for your comments. The following sections of the guidance have been included to monitor safety related outcomes and add to the evidence base. Section 1.1 highlights safety and recommended special arrangements for this procedure. Section 1.2 states that clinicians wishing to undertake the procedure should audit and review clinical outcomes of all patients having NAGP for HIV-related facial lipoatrophy. Section 1.4 states that further research and publication of observational data would be useful.

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6	Consultee 2 British HIV Association	1.3	**Clinicians using this procedure should be trained in the technique of injecting non-absorbable gel polymers** BHIVA response: “There should be evidence of training as opposed to trained and a competency assessment made as above.”	Thank you for your comment. The Committee considered your comment and chose not to amend the guidance.
			Injection should be carried out with strict aseptic technique in an appropriate environment because patients with HIV are commonly immunocompromised. BHIVA response: “By definition they are immunocompromised – anyway, this comment has no bearing as any injectable procedure should be carried out using universal infection control precautions and under strict aseptic technique.	Thank you for your comment. The Committee amended section 1.3 of the guidance as follows: Injection should be carried out with strict aseptic technique in an appropriate environment.

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7	Consultee 2 British HIV Association	2.1	**Prolonged treatment with highly active antiretroviral therapy for HIV…** BHIVA response: “Incorporating in particular the thymidines nucleosides.” **central parts the body (predominantly over the abdomen).** BHIVA response: “The process of fat loss and fat accumulation are different – lipoatrophy only relates to fat loss. This is an important distinction to make to avoid confusion.” **It usually persists after HIV treatment has stopped.** BHIVA response: “In severe cases, restoration of fat after switching away from the causal drugs is likely to be incomplete. – It’s not that the process persists but that the visible return of fat is often imperceptible” **Facial lipoatrophy is commonly seen after HIV treatment.** BHIVA response: “Again, there needs to be specific mention of the responsible drugs otherwise the wrong impression is given to the reader.”	Thank you for your comments. The Committee considered your comments and amended the guidance at section 2.1.1 as follows: 2.1.1 Lipoatrophy is the localised loss of fat from within subcutaneous tissue. It can be a congenital condition or be associated with subcutaneous injections sites. Facial lipoatrophy is commonly seen after HIV treatment, particularly with the older antiretroviral drugs. It involves wasting of the soft tissues of the cheeks, temples and around the eyes, producing changes in appearance that have severe psychological and social consequences for some patients.
8	Consultee 2 British HIV Association	2.2	**The procedure is performed under general or local anaesthesia. Non-absorbable gel polymer is injected with a needle or cannula, deep into the subcutaneous tissue. Strict aseptic technique is used and prophylactic antibiotics are given.** BHIVA response: “The evidence for this is limited? Advise ‘consideration for..’ ”	Thank you for the comment. The Committee considered your comment and chose not to amend the guidance.

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9	Consultee 2 British HIV Association	2.4	**Infection (confirmed by culture) was reported in 16% (5/32) of patients in the cohort study** BHIVA response: “Should reference Clin Infect Dis 2012 September 24th where infectious complications in 267 patients treated with Polyalkylimide (Bio-Alcamid) and Plast. Reconstr. Surg. 129: 101, 2012 which quotes infectious complications on 141 patients treated with polyacrylamide gel. Also systematic review in AIDS patient care STDS 2009.”	Thank you for your comment. The Committee considered removing the conference abstract and adding the Nadarajah JT (2012) study that was recently published to Table 2 of the overview. The second paper cited (De Santis 2012) is already included in table 2 of the overview. The systematic review (Sturm 2009) is included in the appendix as it is not comprehensive and includes evidence on both permanent and semi-permanent dermal fillers.
10	Consultee 3 Clinician	2.4	Under section 2.4 of the document, the Specialist Advisors state "theoretical risks"; this terminology should be changed to "identified" or "known" risks, to strengthen the statement. In addition to the risks listed, others need to be added. We propose that the statement should read: *"Specialist Advisors identified vascular occlusion and skin necrosis, embolism and blindness, chronic granuloma formation, infection with abcess formation and extrusion as known risks of injectable filler treatments. Furthermore, unsatisfactory and short duration of effect are also recognised."*	Thank you for your comment. This section lists only those events which the Specialist Advisers advise us that they consider to be the ‘theoretical events’ associated with the procedure. The additional events you have included (skin necrosis, embolism and blindness, infection with abscess formation and extrusion) were not identified by the Specialist Advisers and therefore cannot be included in 2.4.5.