

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA64; Human growth hormone (somatropin) in adults with growth hormone deficiency

This guidance was issued in August 2003.

The review date for this guidance is 'within 6 months' of the publication of trial data according to the last review update in May 2012.

1. Recommendation

TA64 should be moved to the static list. That we consult on this proposal.

2. Original remit(s)

To appraise the clinical and cost-effectiveness of human growth hormone in its licensed indications for the treatment of growth hormone deficiency in adults.

3. Current guidance

1.1 Recombinant human growth hormone (somatropin) treatment is recommended for the treatment of adults with growth hormone (GH) deficiency only if they fulfil all three of the following criteria.

- They have severe GH deficiency, defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test.
- They have a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease-specific 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire.
- They are already receiving treatment for any other pituitary hormone deficiencies as required.

1.2 The QoL status of people who are given GH treatment should be re-assessed 9 months after the initiation of therapy (an initial 3-month period of GH dose titration, followed by a 6-month therapeutic trial period). GH treatment should be discontinued for those people who demonstrate a QoL improvement of less than 7 points in QoL-AGHDA score.

1.3 Patients who develop GH deficiency in early adulthood, after linear growth is completed but before the age of 25 years, should be given GH treatment until adult peak bone mass has been achieved, provided they satisfy the biochemical criteria for severe GH deficiency (defined as a peak GH response

of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test). After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all the criteria in Section 1.1.

- 1.4 Patients currently receiving GH treatment, for the management of adult onset GH deficiency, whether as routine therapy or as part of a clinical trial, could suffer loss of well being if their treatment were to be discontinued at a time they did not anticipate. Because of this, all NHS patients who are on therapy at the date of publication of this guidance should have the option to continue treatment until they and their consultant consider it is appropriate to stop.
- 1.5 Children with GH deficiency should be treated as outlined in the Institute's guidance on the use of GH in children (NICE Technology Appraisal Guidance No. 42 [Replaced by NICE Technology Appraisal Guidance 188]). At completion of linear growth (that is, growth rate < 2 cm/year), GH treatment should be stopped for 2–3 months, and then GH status should be re-assessed. GH treatment at adult doses should be re-started only in those satisfying the biochemical criteria for severe GH deficiency (defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test), and continued until adult peak bone mass has been achieved (normally around 25 years of age). After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all the criteria set out in Section 1.1.

4. Rationale¹

No new evidence has been found that would justify a review and no there is no indication that there are any ongoing studies whose results might change the guidance.

5. Implications for other guidance producing programmes

There is no proposed or ongoing guidance development that overlaps with this review proposal'.

6. New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from February 2009 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

7. Summary of evidence and implications for review

¹ A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper

The updated literature searches identified a number of new publications, including clinical trials, systematic reviews and meta-analyses. The majority of the newly published research provides evidence on the efficacy and safety of somatropin, including 3 studies of newer somatropin preparations (Beck-Peccoz et al. 2014; Biller et al. 2011; Biller et al. 2013). A number of studies explored key outcomes such as bone mineral density (Barake et al. 2014; Elbornsson et al. 2012; Kuzma et al. 2013; Xue et al. 2013), cardiovascular risk (Gazzaruso et al. 2014; Newman et al. 2011; Schneider et al. 2011), metabolic changes (Chihara et al. 2010; Valle et al. 2009) and sleep (Morselli et al. 2013). The results of these studies are not expected to affect the guidance in Technology Appraisal 64 (TA64). Although the additional information on the effect of somatropin on bone mineral density and cardiovascular risk allows a better understanding of long-term treatment outcomes, both of these outcomes were found to have a very small effect on the results of the economic model for this appraisal.

The effect of growth hormone deficiency and somatropin therapy on quality of life was identified in TA64 as a key uncertainty and priority for research. A number of studies and systematic reviews included quality of life in their reported outcomes, and suggested that somatropin may improve quality of life (Appelman-Dijkstra et al. 2013; Jorgensen et al. 2011; Kokshoorn et al. 2011; Shimatsu et al. 2013). However, there remains a paucity of controlled, comparative evidence, and in particular there is very little evidence on the effects of somatropin compared with placebo. The only randomised, placebo-controlled trial identified in the searches (Filipsson-Nyström et al. 2012) looked specifically at the effect of treatment discontinuation. Consequently, the identified studies are not anticipated to sufficiently address uncertainties about the effect of somatropin on quality of life and would not affect the existing recommendations. No studies have been identified that address the remaining uncertainties and research recommendations in TA64.

Conway *et al.* studied the effects of somatropin on bone mineral density in young adults after completion of linear growth (Conway et al. 2009). This was a key subgroup in TA64. The study found a beneficial effect of somatropin on bone mineral density in this population, and was consistent with the Committee's conclusions in the appraisal. Further studies explored the effects of somatropin in other subgroups: people with diabetes (Barner et al. 2012), women receiving oestrogen or raloxifene (Birzniece et al. 2012), women with a history of acromegaly (Valassi et al. 2012) and people previously treated with pituitary irradiation (Elbornsson et al. 2013). TA64 did not include specific recommendations for these subgroups, and it is not anticipated that these studies would lead to additional recommendations.

Overall, although a number of additional studies have been published, no evidence has been identified that would be anticipated to affect the current guidance on somatropin in adults with growth hormone deficiency.

This finding is consistent with review proposals conducted in 2006 and 2009, which also found no new evidence that would have a material effect on the original guidance. The previous review proposals identified an ongoing study on the effects of growth hormone replacement on quality of life and cardiovascular risk, and therefore proposed to defer the review of TA64 until this study was completed. We now understand that this study has been closed because of problems with recruitment, and so will not affect the guidance in TA64. A number of other ongoing

and unpublished studies have been identified in the current review (Appendix 2), but it is not expected that the results would affect the guidance.

Since TA64 was published, 3 new somatropin preparations have been launched in England, and another has received a marketing authorisation in the European Union. The new preparations include a biosimilar (Omnitrope, Sandoz; referenced to Genotropin) and a once-weekly formulation (Somatropin Biopartners, Biopartners; not currently listed in the BNF). The previously appraised somatropin brands have also released additional formulations, such as alternative injection systems; NICE would not normally appraise such formulations.

8. Implementation

A submission from Implementation is included in Appendix 3.

Prescribing data indicate that most somatropin used in England is prescribed and dispensed in hospitals. The data show a steady increase in the use of somatropin after TA64 was published, although there appears to have been a decline in the overall spending on somatropin between 2009 and 2014.

In addition, a retrospective audit of clinical practice in Scotland was identified in the updated literature searches (Philip et al. 2013). The authors concluded that the use of quality of life assessments has increased since TA64 was published, but most adults taking somatropin did not fulfil all of the criteria for starting and continuing growth hormone replacement specified in the guidance. The results suggest that the guidance has been partially, although not fully, implemented in Scotland.

9. Equality issues

No equality issues have been identified.

GE paper sign off: Janet Robertson, 12 August 2014

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Appendix 1 – explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	Consequence	Selected – ‘Yes/No’
A review of the guidance should be planned into the appraisal work programme. The review will be conducted through the [specify STA or MTA] process.	A review of the appraisal will be planned into the NICE’s work programme.	No
The decision to review the guidance should be deferred to [specify date or trial].	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE’s work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE’s work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	<p>The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review.</p> <p>This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.</p>	No

Options	Consequence	Selected – ‘Yes/No’
The guidance should be updated in an on-going clinical guideline.	<p>Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn.</p> <p>Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).</p>	No
The guidance should be transferred to the ‘static guidance list’.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes

NICE would typically consider updating a technology appraisal in an ongoing guideline if the following criteria were met:

- i. The technology falls within the scope of a clinical guideline (or public health guidance)
- ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement
- iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment
- iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;
 - Spending on a treatment for the indication which was the subject of the appraisal continues to rise
 - There is evidence of unjustified variation across the country in access to a treatment
 - There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed

- The treatment is excluded from the Payment by Results tariff
- v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

Appendix 2 – supporting information

Relevant Institute work

Published

Technology Appraisal TA188. Human growth hormone (somatropin) for the treatment of growth failure in children. Issued May 2010. Review decision July 2013: move to static guidance.

Details of changes to the indications of the technology

Indication considered in original appraisal	Proposed indication (for this appraisal)
<p>“GH is licensed for replacement therapy in adults with severe growth hormone deficiency. Patients with severe GH deficiency in adulthood are defined as patients with known hypothalamic pituitary abnormality and at least one known deficiency of another pituitary hormone excluding prolactin. These patients should undergo a single diagnostic test in order to diagnose the presence of GH deficiency. In patients with childhood onset isolated GH deficiency (no evidence of hypothalamic pituitary abnormality or cranial irradiation), two diagnostic tests should be recommended, except for those having low IGF-1 (a marker of GH response) concentrations (standard deviation score less than -2) who may be considered for one test.</p> <p>Treatment is self-administered by a daily subcutaneous injection. The initial dose is 0.2–0.3 mg (0.6–0.9 IU) daily (typically 0.27 mg [0.8 IU] daily). For the first 2–3 months dosage adjustments are made after monthly assessments of serum levels of IGF-1, and in response to the presence of adverse effects, until a maintenance dose is achieved. The currently used median maintenance dose is 0.4 mg (1.2 IU) daily. GH requirements may decrease with age.”</p>	<p>eBNF (July 2014) says the following: “Adult growth hormone deficiency, by subcutaneous injection, initially 150–300 micrograms daily, gradually increased if required to max. 1 mg daily; use minimum effective dose (requirements may decrease with age).”</p> <p>For an example source, see: SPC for Genotropin, last updated March 2012.</p> <p><u>“Adults</u></p> <p>Replacement therapy in adults with pronounced growth hormone deficiency.</p> <p><i>Adult Onset:</i> Patients who have severe growth hormone deficiency associated with multiple hormone deficiencies as a result of known hypothalamic or pituitary pathology, and who have at least one known deficiency of a pituitary hormone not being prolactin. These patients should undergo an appropriate dynamic test in order to diagnose or exclude a growth hormone deficiency.</p> <p><i>Growth hormone deficient adult patients:</i> In patients who continue growth hormone therapy after childhood GHD, the recommended dose to restart is 0.2 – 0.5 mg per day. The dose should be gradually increased or decreased according to individual patient requirements as determined by the IGF-I concentration.</p> <p>In patients with adult-onset GHD, therapy should start with a low dose, 0.15 – 0.3 mg per day. The dose should be gradually increased according to individual patient requirements as determined by the IGF-I concentration.”</p>

Details of new products

In the original TA64 there were “...four preparations of GH available in the UK for the treatment of adults: Genotropin (Pharmacia), Humatrope (Lilly), Norditropin (Novo Nordisk) and Saizen (Serono)”

eBNF (July 2014) lists the following additional technologies as available:

- NutropinAq (Ipsen)
- Omnitrope (Sandoz – a biosimilar referenced to Genotropin)
- Zomacton (Ferring)

In addition, a once-daily formulation of somatropin (Somatropin Biopartners, BioPartners) has received a marketing authorisation in the European Union.

Registered and unpublished trials

Trial name and registration number	Details
Open-label, Single-arm, Phase IV, Multicenter Trial to Explore the Immunogenicity of the Liquid Formulation of Saizen® in Subjects With Growth Hormone Deficiency (GHD) of Adult Onset. NCT01806298	Phase IV, currently recruiting. Estimated enrolment: 77 Estimated primary completion date: December 2015.
International Cooperative Metabolic Study (iNCMS) of NutropinAq® [Somatropin (rDNA Origin) Injection] Replacement Therapy in Adults With Growth Hormone Deficiency. NCT00455884	Phase IV, completed. Enrolment: 546 Completion date: December 2011. <i>No trace of publication found.</i>
Effect of Growth Hormone Replacement Therapy on Cardiovascular Risk Factors in Adult Patients With Severe Growth Hormone Deficiency: Association With IGF-I Concentration. NCT01877512	Phase IV, completed. Estimated enrolment: 32 Primary completion date: April 2014. <i>No trace of publication found.</i>
International Cooperative Growth Study (iNCGS) Post Marketing Surveillance Program for NutropinAq® [Somatropin (rDNA Origin) Injection]. NCT00455728	Phase IV, currently recruiting. Estimated enrolment: 5250 Primary completion date: December 2099 (ninety-nine).

Trial name and registration number	Details
<p>NordiNet® International Outcome Study- Observational Prospective Study on Patients Treated With Norditropin. NCT00960128</p> <p>A parallel study which appears to be in paediatric patients has suspended recruitment: 'New Consent Forms necessary with new website' NCT00615953</p> <p>The rationale, design and methods for this study have been reported in <i>Clinical Epidemiology</i>.</p>	<p>Observational study, enrolling by invitation.</p> <p>Estimated enrolment: 17000</p> <p>Study start date: April 2006.</p> <p>Primary completion date: December 2016.</p> <p>Cohort is adults and children, taking Norditropin for any condition.</p> <p>Relevant primary outcome: Effect of Norditropin treatment on body weight and body composition in adults [Time Frame: Study outcomes (study endpoints) will be analysed and reported on annual basis. The mean follow up period for study outcomes is expected to be 5 years in accordance with defined duration of the study].</p> <p>Relevant secondary outcome: Effect of Norditropin treatment on quality of life, blood biochemistry and the endocrine system in adults [Time Frame: Study outcomes (study endpoints) will be analysed and reported on annual basis. The mean follow up period for study outcomes is expected to be 5 years in accordance with defined duration of the study].</p>

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Appendix 3 – Implementation submission

1. Routine healthcare activity data

1.1. ePACT data

This section presents electronic prescribing analysis and cost tool (ePACT) data on the net ingredient cost (NIC) and volume of somatropin prescribed and dispensed in hospitals in England between April 2009 and March 2014. Unfortunately no data available prior to the guidance publication in August 2003.

Figure 1 Cost and volume of somatropin prescribed in hospital and dispensed in the community in England between April 2009 and March 2014.

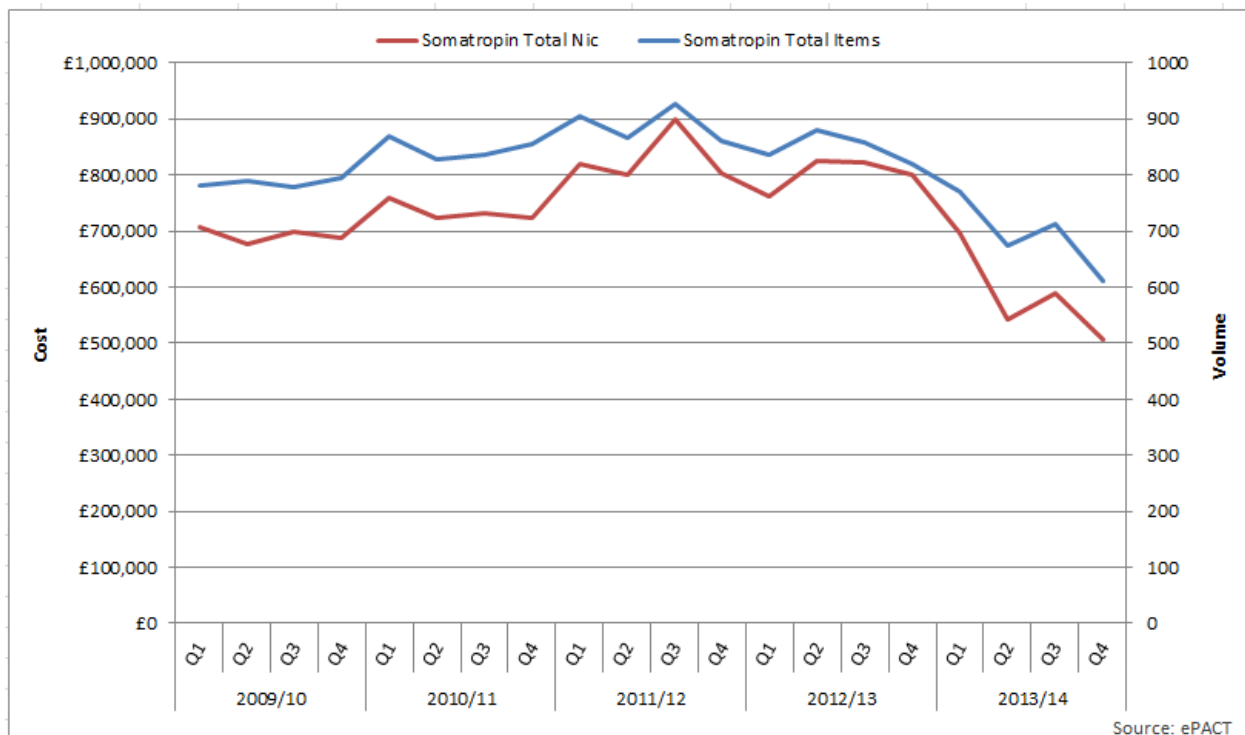
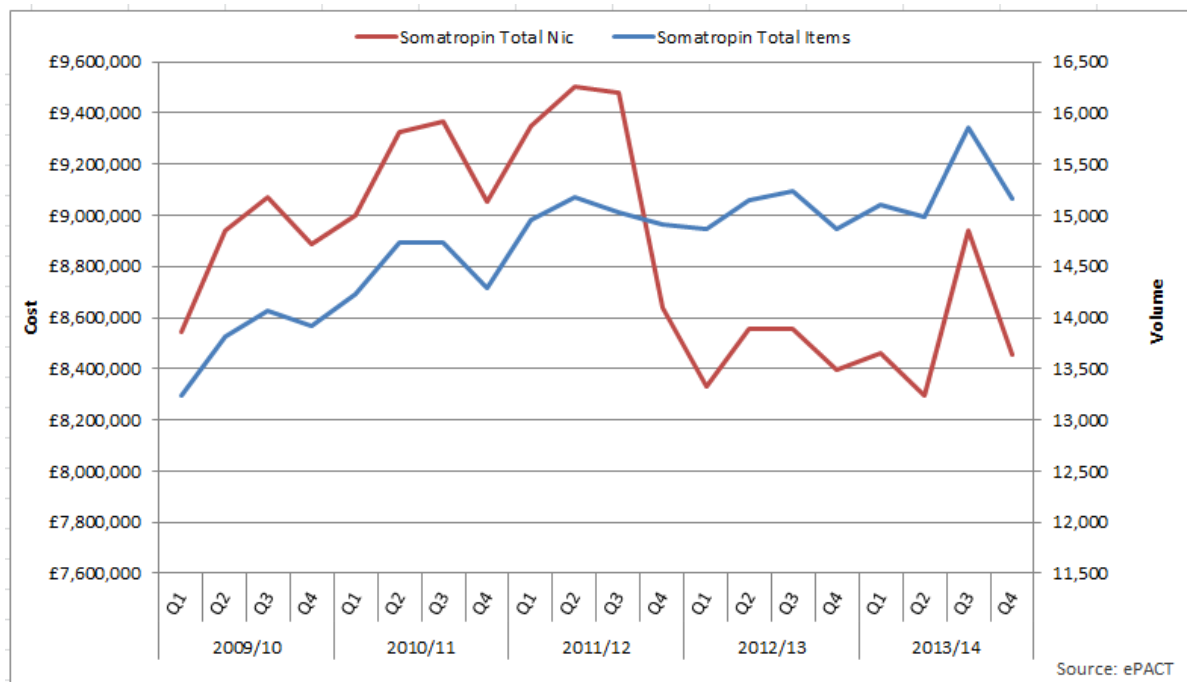


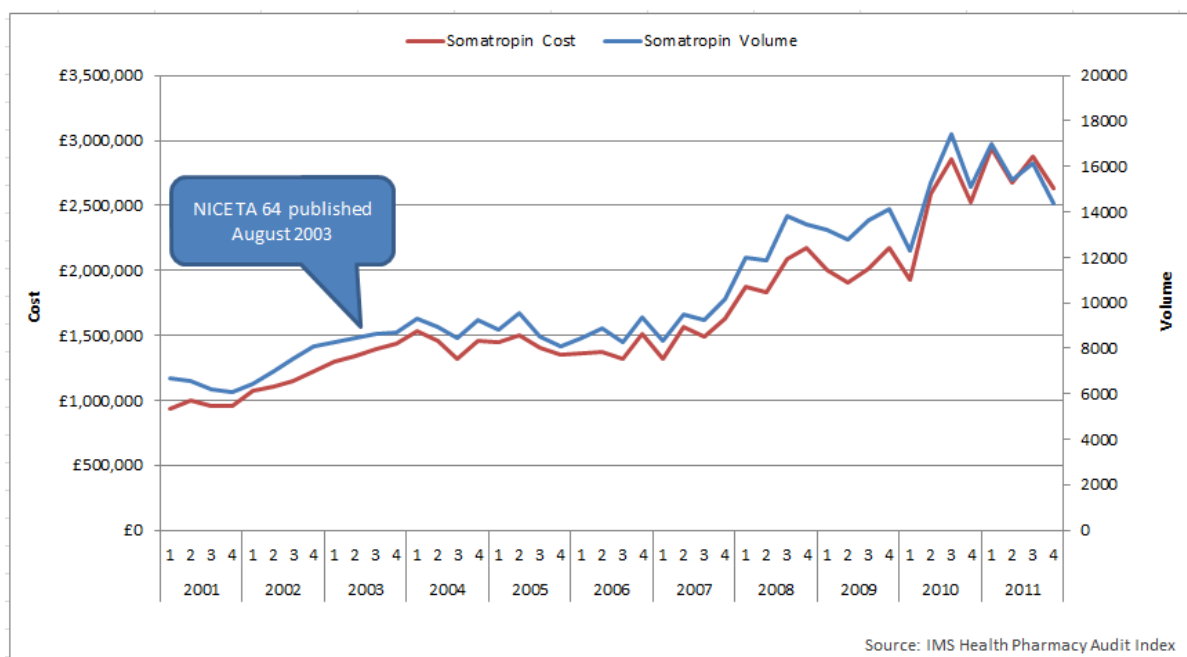
Figure 2 Cost and volume of somatropin prescribed and dispensed in the community England between April 2009 and March 2014.



1.2 Hospital Pharmacy Audit Index data

This section presents Hospital Pharmacy Audit Index (HPAI) data on the net ingredient cost (NIC) and volume of somatropin prescribed and dispensed in hospitals in England between January 2001 and December 2011.

Figure 3 Cost and volume of somatropin prescribed in hospitals in England



2. Implementation studies from published literature

No uptake information was found on the uptake database website for TA 64.

3. Qualitative input from the field team

The implementation field team have not recorded any feedback in relation to this guidance.

4. Implementation studies from shared learning

A search of the shared learning website highlighted no examples of TA64 being implemented.

Appendix A: Healthcare activity data definitions

ePACT

Prescribing analysis and cost tool system

This information comes from the electronic prescribing analysis and cost tool (ePACT) system, which covers prescriptions by GPs and non-medical prescribers in England and dispensed in the community in the UK. The Prescription Services Division of the NHS Business Services Authority maintains the system. PACT data are used widely in the NHS to monitor prescribing at a local and national level. Prescriptions dispensed in hospitals, mental health units and private prescriptions, are not included in PACT data.

Measures of prescribing

Prescription Items: Prescriptions are written on a prescription form. Each single item written on the form is counted as a prescription item. The number of items is a measure of how many times the drug has been prescribed.

Cost: The net ingredient cost (NIC) is the basic price of a drug listed in the drug tariff, or if not in the drug tariff, the manufacturer's list price.

Data limitations (national prescriptions)

PACT data do not link to demographic data or information on patient diagnosis. Therefore the data cannot be used to provide prescribing information by age and sex or prescribing for specific conditions where the same drug is licensed for more than one indication.

IMS HEALTH Hospital Pharmacy Audit Index

IMS HEALTH collects information from pharmacies in hospital trusts in the UK. The section of this database relating to England is available for monitoring the overall usage in drugs appraised by NICE. The IMS HPAI database is based on issues of medicines recorded on hospital pharmacy systems. Issues refer to all medicines supplied from hospital pharmacies to: wards; departments; clinics; theatres; satellite sites and to patients in outpatient clinics and on discharge.

Measures of prescribing

Volume: The HPAI database measures volume in packs and a drug may be available in different pack sizes and pack sizes can vary between medicines.

Cost: Estimated costs are also calculated by IMS using the drug tariff and other standard price lists. Many hospitals receive discounts from suppliers and this is not reflected in the estimated cost.

Costs based on the drug tariff provide a degree of standardization allowing comparisons of prescribing data from different sources to be made. The costs stated in this report do not represent the true price paid by the NHS on medicines. The estimated costs are used as a proxy for utilization and are not suitable for financial planning.

Data limitations

IMS HPAI data do not link to demographic or to diagnosis information on patients. Therefore, it cannot be used to provide prescribing information on age and sex or for prescribing of specific conditions where the same drug is licensed for more than one indication.