



Department  
of Health

# Prescribed Specialised Services Advisory Group

Recommendations to Ministers

March 2017

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# Prescribed Specialised Services Advisory Group (PSSAG)

## Recommendations to Ministers

**Prepared by the PSSAG Secretariat, Department of Health**

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# Introduction

Since its last report was published in March 2016, the Prescribed Specialised Services Advisory Group (PSSAG) has continued to provide advice to Ministers on specialised services and held meetings on 12 May 2016 and 28 October 2016. This report presents PSSAG's recommendations from both meetings and sets out Ministers' decisions on each of the recommendations it made.

In deciding whether it would be appropriate for a health service to be nationally commissioned by NHS England<sup>i</sup> the Secretary of State must have regard to four statutory factors (as set out in section 3B(3) of the National Health Service Act 2006 as amended by the Health and Social Care Act 2012). These are:

- The number of individuals who require the provision of the service or facility;
- The cost of providing the service or facility;
- The number of persons able to provide the service or facility; and
- The financial implications for Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility.

Before deciding to make regulations requiring NHS England to commission such services, the Secretary of State must (a) obtain appropriate advice for that purpose, and (b) consult NHS England. PSSAG was established by the Department of Health in 2013 to provide the Secretary of State with this advice.

The specialised services directly commissioned by NHS England are listed in Schedule 4 to the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, 'the Regulations'<sup>ii</sup>. Ministers obtained advice on the initial list of specialised services to be commissioned by NHS England from 1 April 2013 (set out in the Regulations) from an independent stakeholder group, the Clinical Advisory Group (CAG), established in June 2011 to provide Ministers with this advice.<sup>iii</sup> Following advice from PSSAG and consultation with NHS England, the list of specialised services set out in Schedule 4 was amended with effect on 1 April 2016 to add two new services, to remove adult morbid obesity services (and clarify that surgery for complex obesity in children remains) and to clarify that the heart and lung transplantation service includes mechanical circulatory support.<sup>iv</sup>

It is NHS England's responsibility to determine how these services are commissioned. Service descriptions for each of the specialised services are set out in NHS England's 'Manual for prescribed specialised services' (first published November 2012 and updated in May 2016).<sup>v</sup> The Manual should be considered alongside service specifications, NHS England commissioning policies and the technical requirements NHS England imposes on providers. (References in this report to service descriptions are to the descriptions given in the Manual.)

# Prescribed Specialised Services Advisory Group (PSSAG)

PSSAG is a Department of Health expert committee that was established in 2013 to provide ongoing advice to Ministers on whether services are specialised and should be nationally commissioned by NHS England, rather than locally commissioned by Clinical Commissioning Groups (CCGs).

Membership of the group includes representatives from the Royal Colleges and CCGs, lay members to represent the interests of patients and the general public, and members with financial and technical expertise who can offer assistance with how the specialised elements of a service can be separately identified. The full PSSAG membership is at Annex A.

Evidence and supporting information on services currently prescribed in legislation for direct commissioning by NHS England and any services identified as potentially suitable for such commissioning, is made available to PSSAG from a range of sources. These may include Clinical Reference Groups (CRGs)<sup>vi</sup>, patient groups, clinicians, commissioners and members of the public. The proposals the Group considers are in large part generated by NHS England through its CRGs.

This year, PSSAG began to give consideration to the services previously identified by the CAG for “early review”. These services were generally recommended by CAG for review in two to three years once the new commissioning arrangements were established in 2013. The majority of these were services that CAG recommended for commissioning by NHS England in the first instance with a view to elements being considered for commissioning by CCGs in the future. In addition, CAG recommended three services for commissioning by CCGs in the first instance with a view to elements being considered for commissioning by NHS England in the future.<sup>vii</sup> Further information about PSSAG’s consideration of these services can be found in Section 9.

## Process

PSSAG considers four specific questions:

1. Whether the services currently included on the list of prescribed specialised services set out in legislation should continue to be commissioned by NHS England.
2. Whether there are services currently commissioned by NHS England, which would be more appropriately commissioned by CCGs.
3. Whether there are services currently commissioned by CCGs, which would be more appropriately commissioned by NHS England.
4. Whether there are innovative new treatments and interventions that are not part of existing services and which should be commissioned by NHS England.

When considering if a service is specialised or not the group must review existing services and assess new ones on the basis of the four factors within the National Health Service Act 2006 which are:

- The number of individuals who require the provision of the service or facility;

- The cost of providing the service or facility;
- The number of persons able to provide the service or facility; and
- The financial implications for Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility.

In developing its advice, PSSAG may also consider such matters as:

- How activity can be identified to enable separate contracting, monitoring and payment;
- Likely running costs associated with separate and direct commissioning;
- Defining elements of the service to be commissioned; and
- The number of provider contracts NHS England is likely to need to develop to directly commission the service.

As part of the process in advising the Secretary of State about statutory prescribed services, the group will also consider proposals from NHS England on the formulation of its service descriptions and will provide advice to Ministers on whether the service descriptions (and any proposed changes) are appropriate in respect of the prescribed service.

## Outcomes

This report sets out the recommendations that PSSAG made at its May and October 2016 meetings on the services to be directly commissioned by NHS England. A broad, outline summary is as follows:

1. Alpha-1 antitrypsin deficiency - *recommended for commissioning by NHS England from April 2018*
2. Amelogenesis imperfecta services- *no changes to be made at this time.*
3. Cryopreservation of ovarian tissue- *no changes to be made at this time.*
4. Faecal microbiota transplants service- *no changes to be made at this time.*
5. Neurosciences - adult stroke services- *no changes to be made at this time.*
6. Postural tachycardia syndrome- *no changes to be made at this time.*
7. Services for children, young people and adults- *legal advice sought before final decision.*
8. Services marked for "early review" by the former Clinical Advisory Group- *legal advice sought before final decision*
9. Uterine transplantation service- *recommended for commissioning by NHS England from April 2017*

Ministers have accepted the recommendations set out in this report and in accordance with the National Health Service Act 2006 Ministers have undertaken a formal consultation with NHS England on the proposed changes. In its formal response to the consultation, NHS England confirmed that it supported the recommendations made by PSSAG. PSSAG's recommendations, along with the consultation between the Department of Health and NHS England, inform the development of the necessary statutory instruments to amend Schedule 4 of the Regulations, setting out the specialised services for which NHS England will have commissioning responsibility from April 2016.

# 1. Alpha-1 antitrypsin deficiency services

## Service summary and proposal

Alpha-1 antitrypsin deficiency (also known as alpha-1 proteinase inhibitor (A1PI) deficiency) is a rare, genetic disorder that predisposes individuals to lung and liver disease. This can be severe. NHS England does not currently commission specialised services for people with severe A1PI deficiency and this proposal was for a nationally commissioned specialised service for patients with severe A1PI deficiency.

## View of PSSAG

In formulating its advice to Ministers, PSSAG sought advice from the Royal College of Physicians and the British Thoracic Society along with NHS England's Specialised Respiratory Clinical Reference Group. PSSAG agreed, on the basis of the four statutory factors, that severe or complex alpha-1 antitrypsin deficiency services are suitable for commissioning by NHS England, rather than by CCGs, particularly with respect to the small number of individuals with the severe form of the condition, the high cost of providing the service, the low number of centres with the expertise to treat these patients and the significant financial risk to CCGs if they were required to provide the service. Ministers agreed with PSSAG's advice, however, NHS England has requested that it be allowed more time to identify patients in need of this service and that the services transfer take place in April 2018. As a consequence ministers agreed that commissioning responsibility for severe alpha-1 antitrypsin deficiency services to transfer to NHS England from 1 April 2018.

## Suggested changes

PSSAG recommended that this become a directly commissioned service. Ministers have accepted this recommendation but agreed to NHS England's request for more time to prepare for a transfer. As such, NHS England has agreed to work towards becoming the responsible commissioner from April 2018 to give NHS England time to identify patients and build an appropriate service specification.

## 2. Amelogenesis imperfecta services

### Service summary and proposal

Amelogenesis imperfecta is a collective term for a rare group of conditions affecting the quality or quantity of dental enamel on both the baby and adult teeth. It can occur in isolation of other health problems, but can also occur as part of a syndrome that affects multiple parts of the body, including the kidneys.

PSSAG considered a proposal for a nationally commissioned genetic testing service for amelogenesis imperfecta, which could lead to a better understanding of the clinical burden of this condition and improved patient pathways.

A genetic testing service is currently operational in Leeds via the Yorkshire Regional Genetics Service and this proposal related to the extension of this service to other regions across England.

### View of PSSAG

In formulating its advice to Ministers, PSSAG received advice from the Royal College of Physicians, the Renal Association, the Faculty of General Dental Practice and the Medical Genetics CRG. PSSAG discussed the proposal with regard to the four statutory factors and concluded that this service did not meet the requirements for national commissioning by NHS England. PSSAG was content that the number of people requiring the service was low, but did not feel that the cost of the service was particularly high and although the proposal specified only one centre, PSSAG believed that more could deliver the service if required.

Consideration of the impact on CCGs if they were required to commission this service did not apply in this case as dentistry is commissioned by NHS England. PSSAG noted that it is already possible for a dentist to request a genetic test via a geneticist, so a pathway already exists for this type of test to be requested. As NHS England already funds genetic tests, going down this route would ensure that the test was funded by NHS England, as opposed to individual dentists having to cover the costs.

### Suggested changes

PSSAG recommended that no changes be made at this time. Ministers have accepted this recommendation.

## 3. Cryopreservation of ovarian tissue

### Service summary and proposal

This proposal was for NHS England to have commissioning responsibility for a service to provide cryopreservation of ovarian tissue for children and young adults at high risk of sterility because of cancer treatment, who might be unable to access standard fertility preservation methods because of their age/immaturity or the urgency with which they need to commence treatment.

### View of PSSAG

PSSAG's initial thoughts were that the number of individuals requiring the service appeared to be low, and would be unlikely to increase considerably. PSSAG also agreed that the number of centres able to provide the service was low, but was uncertain about the cost of the service, particularly with respect to the reimplementation aspect of it. PSSAG requested a more detailed description of what the entire service would include including the costs of long term storage of the tissue and a projection of what the costs could be in five and ten years' time. PSSAG also asked for further consideration to be given to the impact on CCGs if they were to commission this service.

This service will be brought back to a future PSSAG meeting.

### Suggested changes

No changes required at the present time.

## 4. Faecal microbiota transplants service

### Service summary and proposal

PSSAG considered a proposal for nationally commissioned faecal microbiota transplants service for use in treating patients with recurrent or refractory *Clostridium.difficile* infection and in clinical trials.

### View of PSSAG

The Group noted that this well established service had the potential to offer great benefit to patients with *C.difficile* infection. PSSAG commented that the at number of people requiring the service was relatively low as was the number of providers. However PSSAG was uncertain about what the costs of treatment would be and whether this would be likely to have a significant impact on CCGs if they were to commission the treatment.

PSSAG requested further information before it would be able to make a recommendation.

This service will be brought back to a future PSSAG meeting.

### Suggested changes

No changes required at the present time.

## 5. Neurosciences - adult stroke services

### Service summary and proposal

NHS England had been undertaking a review of its Identification Rules (IRs) to align them more closely with the Prescribed Specialised Services Manual and to correct errors in the 'logic' underpinning the IRs. NHS England had identified an anomaly in the commissioning of stroke services which meant that under the current IRs, CCGs were responsible for commissioning 88% of stroke activity and NHS England was the responsible commissioner for 12% of the activity. This proposal was for NHS England to clarify in its manual that CCGs should be the responsible commissioner for all stroke activity.

### View of PSSAG

PSSAG was content with NHS England's suggested amendment.

### Suggested changes

NHS England was confident that, whilst a transfer of funding would be necessary, it would not require a transfer of commissioning responsibility as this was just a correction to ensure that only CCGs could be identified as the responsible commissioner for stroke services. An amendment to the Regulations would not be necessary, however NHS England would reflect the clarification in the "Adult specialist neurosciences services" section of its Manual.

## 6. Postural tachycardia syndrome

### Service summary and proposal

PSSAG considered a proposal from PoTS UK for a specialised service for people with PoTS.

### View of PSSAG

PSSAG had previously considered this proposal but was unable to make a recommendation without further information about who the patient group was and what the service would look like.

PSSAG received the requested information and sought the views of the Royal College of Physicians, who in turn had consulted with the Association of British Neurologists, the British Cardiovascular Society and the Association of British Clinical Diabetologists. Taking account of the four statutory factors, PSSAG did not feel that this service met the requirements for national commissioning. After reviewing all of the information it had been presented, PSSAG could not be satisfied that patient numbers were low, as a number of people present with the symptoms of PoTS. Although the number of centres currently available to diagnose and manage people with PoTS was relatively low, PSSAG did not believe the costs of providing the service to be particularly high and certainly not high enough to have a significant impact on CCGs.

PSSAG recognised that awareness of the condition was low and that people with PoTS may not be served well by existing services as the clinical problems could cross several different disciplines. However, PSSAG felt that better access to high quality autonomic function labs that could investigate those who are referred with the symptoms might be of greater benefit to patients, rather than national commissioning by NHS England.

### Suggested changes

PSSAG recommended that this service did not meet the requirements for national commissioning and Ministers accepted the recommendation. No changes to be made to the regulations.

## 7. Services for children, young people and adults

### Service summary and proposal

NHS England informed PSSAG of an anomaly in the Regulations which technically means that it is possible to be classed as a young person and an adult simultaneously. This anomaly applies to 20 services. PSSAG considered a proposal from NHS England to remove the term “young people” from all but one of the regulations and to just refer to children. For this one service (Secure forensic mental health services for young people) it was proposed that the definition of “young people” be changed to individuals aged “up to 19 years”.

### View of PSSAG

PSSAG suggested that it may be content with the proposed changes, subject to legal advice about whether these changes could result in a change of commissioner or a reduced level of service for certain groups.

### Suggested changes

PSSAG recommended that legal advice be obtained on the impact of the changes and on the suggested amendments to the regulations.

## 8. Services marked for "early review" by the former Clinical Advisory Group

### Service summary and proposals

The Clinical Advisory Group for Prescribed Services (CAG), established in June 2011 to offer advice to Ministers on the initial list of services for NHS England to commission from April 2013, had recommended a handful of services for "early review". These were services where the CAG had considered that once established, CCGs could be better placed to commission the services (or elements thereof) as by then some consistency in quality and standards would have been achieved. CAG recommended that these services be reviewed in around 2-3 years from April 2013, which was when the new commissioning arrangements had come into force.

NHS England advised PSSAG that the commissioning landscape had changed significantly since CAG had suggested an early review of certain services and that its establishment of Sustainability and Transformation plans (STPs) would enable a number of specialised services to be planned and commissioned on a wider footprint than CCG level.

### View of PSSAG

PSSAG acknowledged that a more collaborative approach could make sense for a number of services, but did not want to risk levels of commissioning becoming blurred. PSSAG was not content for any change to responsible commissioner to be made without full consideration of each service with regards to the four statutory factors.

PSSAG asked NHS England to bring further detail on how its work on a more collaborative approach to commissioning might work for this handful of services.

### Suggested changes

PSSAG recommended no changes to the regulations at the current time.

## 9. Uterine transplantation services

### Service summary and proposal

PSSAG considered a proposal for a nationally commissioned uterine transplantation service for women with absolute uterine factor infertility. PSSAG noted that this service was still in its infancy and that there could be legal and ethical issues to be worked through before the service could become fully operational.

### View of PSSAG

PSSAG discussed the service with regard to the four statutory factors and agreed that the number of people requiring the service was low, whilst the cost of providing the service was high. The number of people able to provide the service was low as there is just one team currently undertaking research in this area in the UK. PSSAG anticipated that the impact on CCGs, if they were required to commission this service, could be significant.

As this service was about to undergo a trial, PSSAG felt that it was too early for NHS England to begin commissioning it. However, PSSAG agreed that if this service should be commissioned by the NHS, then NHS England should be the responsible commissioner.

PSSAG agreed to recommend to Ministers that this service did meet the requirements for national commissioning with regard to the four statutory factors.

### Suggested changes

PSSAG recommended that Uterine Transplantation be directly commissioned by NHS England. Ministers agreed to this recommendation and it will be added to the regulations to come into effect from April 2017.

# Annex A - Prescribed Specialised Services Advisory Group Membership

## Chair

Professor Sir Ian Gilmore

## Members

Dr J E Tim Burke (clinical commissioning group – south)

Dr Christine Moss (clinical commissioning group – midlands and east)

Dr Chris Clayton (clinical commissioning group – north)

Professor Paul O'Flynn FRCS (Royal College of Surgeons of England)

Professor Bronwyn Kerr (Academy of Medical Royal Colleges)

Dr Andrew Goddard (Royal College of Physicians)

Professor Tim Barrett (Royal College of Paediatrics and Child Health)

Helen Donovan (Royal College of Nursing)

Dr Ashok Roy (Royal College of Psychiatrists)

Professor Bhaskar Choubey (lay representative)

Vacancy (lay representative)

Steve McNeice (lay representative)

Manoj Mistry (lay representative)

Tabitha Gardner (NHS England Finance)

Teresa Fenech (NHS England Nursing)

Ceri Townley (NHS England Informatics)

Fiona Marley (NHS England Specialised Commissioning)

# References

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<sup>i</sup> NHS England is the operational name used by the National Health Service Commissioning Board, created under section 1H of the National Health Service Act 2006, as amended by the Health and Social Care Act 2012.

<sup>ii</sup> SI 2012/2996. Copies of legislation may be purchased from HMSO. Additionally, a copy of this statutory instrument, in its original form, is available at: <http://www.legislation.gov.uk/ukxi/2012/2996/contents/made>. There are other amendments to this statutory instrument but they are not listed here as they are not relevant. Further, relevant amendments to SI 2012/2996 are to be found in SI 2014/452 and SI 2015/415. A further amending statutory instrument is in the process of being made at the time of publication of this document and will be available at [www.legislation.gov.uk](http://www.legislation.gov.uk).

<sup>iii</sup> National commissioning of specialised services: report from the Clinical Advisory Group for Prescribed Services: <https://www.gov.uk/government/publications/national-commissioning-of-specialised-services-report-from-the-clinical-advisory-group-for-prescribed-services>

<sup>iv</sup> The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) (Amendment) Regulations 2016 (SI 2016/293) available at: <http://legislation.data.gov.uk/ukxi/2016/293/made/data.htm?wrap=true>

<sup>v</sup> The latest version of the Manual for Prescribed Specialised Services is available at

<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf>

A postal copy may be requested by telephoning 0300 311 22 33 (Monday to Friday 8am to 6pm, excluding English Bank Holidays) or writing to the Board at PO Box 16738, Redditch, B97 9PT,

<sup>vi</sup> NHS England's Clinical Reference Groups (CRG) cover the full range of specialised services and are responsible for providing NHS England with clinical advice regarding the services commissioned by NHS England. The CRGs are made up of clinicians, commissioners, Public Health experts and patients and carers, and are responsible for the delivery of key 'products' such as service specifications and commissioning policies, which enable NHS England to commission services from specialist providers through the contracting arrangements overseen by its Area Teams

<sup>vii</sup> National commissioning of specialised services: report from the Clinical Advisory Group for Prescribed Services: <https://www.gov.uk/government/publications/national-commissioning-of-specialised-services-report-from-the-clinical-advisory-group-for-prescribed-services>.