



Department
of Health &
Social Care

Prescribed Specialised Services Advisory Group

Recommendations to Ministers

March 2018

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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 2017, the Prescribed Specialised Services Advisory Group (PSSAG) has continued to provide advice to Ministers on specialised services and held meetings on 10th May and 26th October 2017. 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 Englandⁱ 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'ⁱⁱ. 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.ⁱⁱⁱ Following advice from PSSAG and consultation with NHS England, the list of specialised services set out in Schedule 4 was amended with effect on 1st April 2017.

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 October 2017).^{iv} The Manual should be considered alongside service specifications, NHS England commissioning policies and the technical requirements NHS England imposes on providers.

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)^v, 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.

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 2017 meetings on the services to be directly commissioned by NHS England, and the outcomes of Secretary of State's consultation with NHS England. A broad, outline summary is as follows:

1. Alpha-1 antitrypsin deficiency – *to be commissioned by NHS England from 1st April 2019*
2. Gonadal Tissue Cryopreservation Services for children and young people at high risk of gonadal failure due to treatment or disease – *to be commissioned by NHS England from 1st April 2020*
3. Psychological medicine inpatient services for severe and complex presentations of medically unexplained physical symptoms - *to be commissioned by NHS England from 1st April 2020*
4. Specialist Adult Haematology services – *to be commissioned by NHS England from 1st April 2020*
5. Termination services where the expectant mother has significant comorbidities that require critical care and/or medical support - *to be commissioned by NHS England from 1st April 2018*
6. Changes to prescribed specialised service names in regulations
7. Spina Bifida – *no changes at this time*
8. Faecal microbiota transplantation services – *no changes at this time*

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 2018, with further services transferring between then and 1st April 2020.

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 in 2017, 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 NHS England's request that it be allowed more time to prepare for the transfer of responsibility and that the transfer of the service take place in April 2019.

Suggested changes

PSSAG had previously recommended that this should 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 is continuing to work towards becoming the responsible commissioner from April 2019.

2. Gonadal Tissue Cryopreservation Services for children and young people at risk of gonadal failure due to treatment or disease

Service summary and proposal

Ovarian (or 'gonadal') tissue Cryopreservation for children and young adults at high risk of fertility problems resulting from treatment for cancer or other life threatening illnesses is currently available through two main centres; Oxford provides a service for patients in England, Wales and Northern Ireland whilst Edinburgh has a programme for patients in Scotland. Whilst the majority of referrals are pre-treatment for malignant disease, there is a growing number of patients being referred with non-malignant conditions such as bone marrow failure syndromes or sickle-cell disease where curative treatment involves stem cell transplantation.

View of PSSAG

PSSAG discussed the proposal and agreed that it fit the four tests required by law. Following positive feedback from the Royal College of Obstetricians & Gynaecologists, PSSAG concluded that this service should be a Specialised Service commissioned nationally by NHS England.

Suggested changes

PSSAG recommended that the ovarian tissue cryopreservation service proposed should be added to the list of Prescribed Specialised Services. Ministers agreed to PSSAG's recommendation, and to NHS England's request that commissioning responsibility for this service should transfer to it on 1st April 2020.

3. Psychological medicine inpatient services for severe and complex presentations of medically unexplained physical symptoms

Service summary and proposal

This service delivers multidisciplinary care and treatment for people with particularly severe and complex presentations of medically unexplained physical symptoms (MUS), and is currently provided by the Leeds and York Partnership NHS FT (LYPFT), from a general hospital facility within Leeds General Infirmary, which is part of the Leeds Teaching Hospitals NHS Trust.

View of PSSAG

PSSAG discussed the proposal and felt that the proposed service would help meet the needs of a group of patients who are often not assessed by psychiatrists but would benefit from the skills of liaison psychiatry. PSSAG considered that an advantage of this service becoming specialised would be that NHS England could streamline the service and likely make the process run more smoothly. PSSAG agreed that the service met the four factors, and in particular that the number of patients needing the service and the number of centres able to provide it was low. The Group recognised the need for clear communication regarding the availability of the service and awareness-raising at the CCG/ STP level.

Suggested changes

PSSAG recommended that psychological medicine inpatient services for severe and complex presentations of medically unexplained physical symptoms should be added to the list of Prescribed Specialised Services. NHS England has stated that accurately identifying the cohort of patients will be a challenge because they can present across the range of NHS provision. NHS England and Ministers subsequently agreed that given limited parliamentary time and in order to enact PSSAG's recommendation, the service should be included in the updates to the list of prescribed specialised services in regulations, but for commissioning responsibility to only transfer on 1st April 2020. They also agreed that if, closer to the time, NHS England is unable to take on commissioning responsibility by this date, NHS England can write to Ministers outlining the reasons for this so that Ministers can consider applying for Parliamentary time to amend the date.

4. Specialist Adult Haematology services

Service summary and proposal

Adult specialised haematology services are not currently prescribed in regulations, and CCGs commission all adult haematology services (except in a few prescribed cases). NHS England currently commissions the majority of haematology services for children and young people and all rare cancer services. In September 2013, PSSAG considered a proposal from NHS England that it should commission a highly specialist haematology service for adults, to provide for greater alignment between the adult and children's services (which were already prescribed).

This would include the following rare conditions:

- Thrombotic thrombocytopenic purpura (TTP) - a rare blood disorder resulting in clots that cause damage to the kidney, heart and brain.
- Langerhans' cell histiocytosis (LCH) - a cancer-like condition in which an abnormal increase in immune cells causes organ damage.

View of PSSAG

PSSAG had agreed, on the basis of the four statutory factors, that adult specialised haematology services are suitable for commissioning by NHS England, rather than by CCGs, particularly with respect to the small number of individuals requiring the provision of the service, the high cost of providing the service, the very small number of individuals with the expertise to treat these patients and the significant financial risk to CCGs if they were required to provide the service. PSSAG recommended that NHS England commission an adult highly specialist haematology service including the aforementioned rare conditions. Ministers agreed with PSSAG's advice and made the decision for commissioning responsibility for adult specialised haematology services.

NHS England has stated that it needed more time to prepare for taking on commissioning responsibility for adult specialised haematology as the transfer of the service proving more difficult than initially envisaged, but has now agreed to take this on from 1st April 2020. NHS England requested this to allow for the service to go through NHSE's November prioritisation round and for the procurement of providers.

Suggested changes

Ministers have agreed to NHS England to take on commissioning responsibility for specialist adult haematology services from 1st April 2020.

5. Termination services where the expectant mother has significant comorbidities that require critical care and/or medical support

Service summary and proposal

The proposal considered by PSSAG was that NHS England - rather than Clinical Commissioning Groups (CCGs) - should become the responsible commissioner of some termination services: terminations (surgical and medical) where the expectant mother has significant comorbidities that require critical care and/or medical support. These would include women with cardiac, liver and respiratory conditions and those with high BMIs. PSSAG was informed that there is currently only one provider able to offer late surgical termination in women who may also require critical care support and/or input from medical specialties.

View of PSSAG

PSSAG discussed the merits of national commissioning of this service. PSSAG considered the four factors, and in particular recognised that the number of patients and the number of persons able to provide the service is low. The Group raised questions around the need for clarity regarding how this service fits in with the wider system and how clinicians and women know when this specialist service should be used and when termination of pregnancy services should be provided by the local NHS, and emphasised the need for clear eligibility criteria. PSSAG recognised that there is an inequity of provision of these services across the country and this service would reduce this inequity.

Suggested changes

PSSAG concluded that this service met the four criteria and that it should be nationally commissioned by NHS England, but that it should review the service in a number of years' time in case more treatment centres are established. NHS England agreed to take on commissioning responsibility for this service from 1st April 2018.

6. Specialist genetic services

Service summary and proposal

At present, NHS England commissions tests ordered by clinical geneticists and genetic counsellors and other clinicians funded through specialised commissioning.

Where genetic tests are ordered by a clinician other than a clinical geneticist or genetic counsellor, the test forms part of the pathway for the referring specialty. NHS England commissions the test where the referrer is referring as part of another service commissioned by NHS England.

Currently, CCGs commission the test where the referrer is a primary care or secondary/tertiary care clinician referring from a service that is not commissioned by NHS England.

The proposal is for NHS England to commission all genetic tests so that improvements can be made through a single national procurement process in:

- access by patients to genetic tests;
- provision of genetic tests;
- the cost of genetic tests;
- appropriate use of genetic tests.

View of PSSAG

PSSAG considered the proposal and agreed that considered in the whole, the proposal met the four tests, and that in particular the cost of providing genetic tests is high.

Suggested changes

PSSAG recommended that NHS England should be the responsible commissioner for all specialist genetic services. NHS England agreed that commissioning responsibility for this service should transfer on 1st April 2018. This change will be reflected in regulations by amending the name of 'specialist genetic services' to 'clinical genomic services', which NHS England advised better reflects how the service is described by clinicians.

7. Changes to prescribed specialised service names in regulations

Service summary and proposal

At its May and October meetings, PSSAG considered proposals from NHS England to amend the names of some prescribed specialised services in regulations in order to better reflect the service being commissioned or how it is described by the relevant professions. For example, the proposal requested that 'Hand transplantation for adults' should be amended to 'Hand and upper limb transplantation service (adults)' to better describe the service being commissioned.

View of PSSAG

PSSAG discussed the changes to service names and sought views of relevant stakeholders on some of the name changes that could have been questioned by patients.

Suggested changes

PSSAG agreed to the name changes, except for one on which the Secretariat to PSSAG is seeking further stakeholder views. In order to allow for further legal consideration of potential unintended implications of the name changes, the changes will be considered for inclusion in regulations when they are amended next after spring 2018.

8. Spina Bifida

Service summary and proposals

PSSAG had previously considered whether an element of service provision for spina bifida patients should become specialised. Much of care for patients with spina bifida is already prescribed as a specialised service, but there were aspects of urology care that are not.

View of PSSAG

NHS England has not so far been able to identify these sufficiently to include them within the scope of spina bifida services. PSSAG discussed what the specialised element is, and the need to clearly identify a mechanism to identify patients suitable for the specialised service. Data provision is inadequate at this time, meaning it is not possible to move forward with the discussion of elements of spina bifida care as a specialised service. PSSAG discussed and concluded that patients were unlikely to be missing out on services, and asked the Secretariat to seek stakeholder input to gauge their view on not pursuing specialisation.

Suggested changes

No changes required at the present time.

9. Faecal microbiota transplantation services

Service summary and proposal

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

View of PSSAG

The Group had previously considered this proposal and noted that this well established service had the potential to offer great benefit to patients with *C. difficile* infection. PSSAG commented that the 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 continued to discuss the proposal at its May meeting. PSSAG noted that it looked like there may be alternative funding routes for faecal microbiota transplants. The Secretariat therefore facilitated contact between NHS England and the authors of the proposal to discuss this further.

Suggested changes

No changes required at the present time.

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)

Amit Bhagwat (lay representative, appointed after October meeting)

Tabitha Gardner (NHS England Finance)

Teresa Fenech (NHS England Nursing)

Ceri Townley (NHS England Informatics)

Fiona Marley (NHS England Specialised Commissioning)

References

ⁱ 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.

ⁱⁱ 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/ukSI/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.

ⁱⁱⁱ 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>

^{iv} 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,

^v 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