AGENDA ITEM 7.

NHS Southend Clinical Commissioning Group

GOVERNING BODY IN PUBLIC - PART I

SERVICE RESTRICTION POLICIES

Date of the meeting	01/12/2016
Author	Dr Mark Lim
Sponsoring Board Member	Robert Shaw – Director of Acute Commissioning and Contracts
Presented by	Robert Shaw – Director of Acute Commissioning and Contracts
Purpose of Report	This paper contains recommendations in relation into service restrictions from Clinical Executive.
Recommendation	Following discussion at Clinical Executive, Governing Body is asked to: 1) **Note** that service restrictions, or changes to existing service restrictions, for male sterilisation, female sterilisation and sleep apnoea were considered and that Clinical Executive recommended there be no change to existing policy. 2) **Note** that no changes have been made to criteria under which patients would receive hip injections, varicose vein surgery and breast procedures (excluding gynaecomastia) but **approve** the implementation of a **prior approval process** to ensure that patients meet the existing criteria. 3) **Note** that the CCG will commence discussions in relation to best use of spinal cord stimulators. 4) **Approve** a policy that patients undergoing total shoulder replacement should have at least twelve weeks of non-surgical treatment unless the existing joint is affected by trauma, infection or cancer. 5) **Approve** the commencement of consultation on service restrictions for toric lens implantation during cataract surgery, spinal injections for back-related pain, and gynaecomastia for reasons of lack of evidence in relation to clinical effectiveness. 6) **Approve** the commencement of consultation on service restrictions for bariatric surgery and assisted conception (including *in vitro* fertilisation) for reasons of affordability. 7) **Note** that if (5) - (6) are approved then the Governing Body will receive a report of the consultation, with an updated equalities impact assessment (including inequalities) and quality impact assessment reflecting the findings of the consultation.
Stakeholder Engagement	Proposals for Stakeholder Engagement are contained within body of the paper.
Previous GB / Committee/s, Dates	Clinical Executive 15th September 2016, 10th October 2016

Monitoring and Assurance Summary

This report links to the following Assurance Domains	• Quality • Equality and Diversity • Engagement • Outcomes • Governance • Partnership-Working • Leadership

I confirm that I have considered the implications of this report on each of the matters below, as indicated:	**Yes** [e.g. ✓]	**Any action required?**	
		Yes Detail in report	**No**
All three Domains of Quality (Safety, Quality, Patient Experience)	✓		
Board Assurance Framework / Risk Register	✓		✓
Budgetary Impact	✓	✓	
Legal / Regulatory	✓	✓	
People / Staff	✓		✓
Financial / Value for Money / Sustainability	✓	✓	
Information Management &Technology	✓		✓
Equality Impact Assessment	✓	✓	
Freedom of Information	✓		✓

Initials: ML

Introduction

1.1. Excluding medicines, there are currently over 220 clinical areas which are covered by service restriction policies across Anglia and the Ceremonial County of Essex.

1.2. Service restrictions can be put in place for a number of reasons, including unwarranted variation in clinical practice, lack of evidence supporting particular procedures, or prohibitive costs.

1.3. Under current arrangements there are some circumstances where different Clinical Commissioning Groups prioritise different services, but differing populations have differing needs and differing budgets. Not having criteria for a particular service does not prevent a postcode lottery, because differing individuals with the same health needs might still receive differing treatments in the absence of criteria within or between areas.

1.4. The Clinical Commissioning Group exercises its clinical judgment in relation to when it is appropriate to implement a service restriction. Typically this is more likely to occur when evidence for a particular treatment is marginal, or the cost of a treatment is sufficiently high that reductions to other services might need to be made in order to keep within budget, or the presence of alternatives which are either more effective or cost-effective.

1.5. On 15th September 2016, Clinical Executive identified fourteen service areas for which the Clinical Commissioning Group should consider changes on the service restriction policy, for which existing policies existed for thirteen.

1.6. Detailed information was considered for each of the fourteen service areas at Clinical Executive on 10th November 2016. Recommendations which are listed later in the report and in the appendix.

Report

2.1 Appendix 1 contains the full information discussed by Clinical Executive.

2.2 In short:

- Male and female sterilisation was considered for restriction but there was evidence of favourable effectiveness and cost-effectiveness compared to other forms of contraception, and unwanted pregnancy had a significant human and financial cost.

- Sleep studies under 18 were considered for restriction, especially as many other CCGs had a policy. Clinical Executive noted that the current activity levels likely indicated that this investigation was being used sparingly and appropriately – namely when there is significant uncertainty between primary snoring and obstructive sleep apnoea.

- Existing policies on hip injections, varicose vein surgery and breast procedures reflected an appropriate prioritisation of those with the greatest clinical need. The CCG will ensure that these are being followed by ensuring that the clinical details are correct prior to surgery ("prior approval").

- There is evidence supporting non-surgical treatment for shoulder pain so for patients without trauma, cancer nor infection it proposed that non-surgical treatments are tried first.

- The evidence for spinal cord stimulators is limited to a small number of specific conditions. Whilst the CCG will fund patients who meet the NICE Guidelines published eight years ago, which included some conditions not directly supported the accompanying evidence, we will seek constructive discussions with clinicians on how less expensive and more effective treatments could be used.

- The existing policy for surgical correction of gynaecomastia uses a classification. This classification system does not appear to support any form of correlation with morbidity nor outcomes from surgery.

- Toric lenses, which are sometimes implanted in cataract surgery patients for the purposes of correcting astigmatism at the same time, lack long-term data on effectiveness.

- Back injections for back-related pain are not supported by strong evidence.

2.3 That assisted conception, can, in selected patients, increase

Conclusion

3.1 Following discussion at Clinical Executive, Governing Body is asked to:

- **Note** the appendix which contains the evidence considered by Clinical Executive.
- **Note** that service restrictions, or changes to existing service restrictions, for male sterilisation, female sterilisation and sleep apnoea were considered and that Clinical Executive recommended there be no change to existing policy.
- **Note** that no changes have been made to criteria under which patients would receive hip injections, varicose vein surgery and breast procedures (excluding gynaecomastia) but

approve the implementation of a **prior approval process** to ensure that patients meet the existing criteria.

- Note that the CCG will commence discussions in relation to best use of spinal cord stimulators.
- **Approve** a policy that patients undergoing total shoulder replacement should have at least twelve weeks of surgical treatment unless the existing joint is affected by trauma, infection or cancer.
- **Approve the commencement of consultation** on service restrictions for toric lens implantation during cataract surgery, spinal injections for back-related pain, gynaecomastia for reasons of lack of evidence in relation to clinical effectiveness.
- **Approve the commencement of consultation** on service restrictions for bariatric surgery and assisted conception (including *in vitro* fertilisation) for reasons of affordability.
- **Note** that if the previous two points are approved, then the Governing Body will receive a report of the consultation, with an updated equalities impact assessment (including inequalities) and quality impact assessment reflecting the findings of the consultation. A draft has been provided to inform discussion.

Author's name and Title : **Dr Mark Lim and Lynne Smith**
Date : **23rd November 2016**
Telephone Number : **01702 314299**

APPENDICES	
Appendix 1	Draft QIA
Appendix 2	Draft EIA IVF
Appendix 3	Draft EIA Service Restriction Policy
Appendix 4	Evidence for NHS England

Quality Impact Assessment - Tracker

To be completed by the Clinical Lead and the Project Manager. Please complete this tracker for all quality indicators that have identified a negative impact, just for that line. If no negative impact has been identified it is not necessary to complete this tracker.

Once completed the risks from this section should be included in the individual project risk log to ensure they are monitored and mitigated appropriately. In addition they should be copied and pasted into the overall QIA risk tracker to ensure they are reported and tracked by the Transformation PMO Team.

Risk Assessment Matrix

	Risk matrix		Severity / Impact / Consequence				
Likelihood of recurrence			None/Near Miss	Low	Moderate	Severe	Catastrophic
		SCORES	1	2	3	4	5
	Rare	1	1	2	3	4	5
	Unlikely	2	2	4	6	8	10
	Possible	3	3	6	9	12	15
	Likely	4	4	8	12	16	20
	Certain	5	5	10	15	20	25

	Risk Scores
Very Low Risk	1-3
Low Risk	4-6
Moderate Risk	8-12
High Risk	15-25

QIA Tracker DRAFT

Project Name	Negative Impact area	Description of negative impact and or risk	Likelihood	Impact	Risk Rating	Mitigating actions/controls	Residual Risk Rating	Escalation & risk tracking	Corresponding metric(s)	Tracking / monitoring forum	Risk owner
Service Restriction Policy review	NICE Guidance and Quality Standards, VTE, Stroke, Dementia	A voluntary discussion in relation to NICE TAG 159 is sought.	4	3	8	Discussion with providers, supported by public health analysis	3 x 2	The results of discussions will be reported to Clinical Executive.			ML
Service Restriction Policy review - Bariatric Surgery	NICE Guidance and Quality Standards, VTE, Stroke, Dementia	Bariatric surgery access criteria are more strict than NICE guideline 189.	5	3	10	Clear explanation to the public of the number of people who would potentially be eligible for bariatric surgery using existing BMI and comorbidity criteria alone, and the potential cost. Explanation that surgery is still available in those for which it provides the best value for money.	5 x 2	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Bariatric Surgery	Clinical Outcomes / Helping people recover from ill health/ injury and preventing people from dying prematurely	There may be a cohort of patients with a BMI of 35-40 with comorbidity or 40 without co-morbidity for whom bariatric surgery would now become exceptional.	3	4	12	The CCG has selected the population most likely to gain significant benefit from the surgery. Though they would remain at elevated risk compared to the general population, the benefit of surgery in these groups is less than those for a BMI of 40 and above and with diabetes. Detailed consideration of potential hypertension, pre-diabetes and mental health problems need more detailed consideration prior a policy position being agreed.	3 x 4	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			
Service Restriction Policy review - Bariatric Surgery	Access to services - equality impact	It is difficult to tell at this stage whether this will reduce inequality or increase inequality. Most evidence from publicly funded healthcare systems shows that richer socieconomic groups are more likely receive bariatric surgery, despite having lower prevalences of obesity. A strict criteria could lead to a 'levelling' of usage, or exacerbate the gradient.	2	3	6	Having only 7 patients that currently have the surgery, it is difficult to undertaken meaningful analysis. The consultation could help to generate a better understanding of the local situation.	2x2	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	NICE Guidance and Quality Standards, VTE, Stroke, Dementia	NICE Guideline 156 (relating to fertility treatment) would not be followed in full due to affordability.	5	4	20	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	5 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Clinical outcomes	Patients who under old criteria, may previously have had specialist fertility services including IVF, would potentially not have access to a service that could improve their chances of pregnancy.	5	4	20	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	5 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS

Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Patient feedback (e.g. FFT, NHS Choices, comments, compliments concerns, complaints, national and local surveys)	Feedback from patients, in relation to the clinical outcomes and NICE Guidance, and their personal experience,	3	4	12	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	3 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Patients, Carers and Public engagement	More information on this is required and would need to be collected through consultation.	3	4	12	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	3 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Persons physical and mental health and emotional wellbeing	More information on this is required and would need to be collected through consultation.	3	4	12	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	3 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Social and economic wellbeing	More information on this is required and would need to be collected through consultation.	3	4	12	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	3 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Domestic, family and personal relationships	More information on this is required and would need to be collected through consultation.	3	4	12	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	3 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS
Service Restriction Policy review - Specialist Fertility Treatment (Assisted Conception, including IVF)	Personal contribution to society including sustainability	More information on this is required and would need to be collected through consultation.	3	4	12	The CCG will collect information on the impact to patients and services, if the Governing Body agrees to proceed with consultation on this issue.	3 x 3	Governing Body will receive the report of the consultation, if it agrees to proeceed with this.			RS

Quality Impact Assessment Checklist

To be completed by the Clinical Lead and Project Manager

Please complete this tracker for all projects, to identify whether there could be a potential impact on the quality indicators shown.

If no negative impacts are identified then it is not necessary to complete the next tab - QIA Tracker

Project Name	Service Restriction Policies (December 2016) DRAFT
Portfolio (bucket)	Acute Commissioning and Contracts
Date	21st November 2016 (Draft - will be updated if further impacts identified through consultation)

Quality indicators to be risk assessed

		Quality Impact Assessment			Project Manager Comments	QIA Panel Comments
		Please 'X' ONE for each			Name: Dr Mark Lim	Name:
		Chance of Impact on Indicator			Date: 21/11/2016	Date:
Risk to	**Quality Indicator**	**Positive Impact**	**No Impact**	**Negative Impact**	**Comments (if required) from the person completing the QIA assessment**	**Comments by the Quality Team or QIA panel approving the QIA**
PATIENT SAFETY	**Patient safety adverse events including avoidable harm and Patient Safety Alert Services (PSAS)**		x			
	Medicine management and safe administration		x			
	Mortality HSMR/SHMI		x			
	Any Infection control issues including MRSA/C*diff*		x			
	CQC: Visits and Registration		x			
	NHSLA / CNST		x			
	Essential training		x			
	Workforce (vacancy turnover absence and revalidation)		x			
	Safe, clean, comfortable and well maintained environments/equipment		x			
CLINICAL EFFECTIVENESS	**NICE Guidance and Quality Standards, VTE, Stroke, Dementia**			x	NICE Guideline 156 (relating to fertility treatment) would not be followed in full due to affordability. A voluntary discussion in relation to NICE TAG 159 is sought. Bariatric surgery access criteria are more strict than NICE guideline 189.	
	Helping people recover from ill health/ injury and preventing people from dying prematurely			x	There may be a cohort of patients with a BMI of 35-40 with comorbidity or 40 without co-morbidity for whom bariatric surgery would now become exceptional. Though they would remain at elevated risk compared to the general population, the benefit of surgery in these groups is less than those for a BMI of 40 and above and with diabetes.	
	Other Outcome Guidance e.g. PROMs		x			
	Other external accreditation e.g. RCN		x			
	National clinical audit/research and development		x			
	Clinical outcomes			x	NICE Guideline 156 (relating to fertility treatment) would not be followed in full due to affordability.	

	Breastfeeding rates		x				
	Emergency bed days		x				
	Length of stay		x				
	Emergency re-admissions (30 day)		x				
	Minor Injuries Standards		x				
	Day case rates		x				
PATIENT EXPERIENCE	Patient feedback (e.g. FFT, NHS Choices, comments, compliments concerns, complaints, national and local surveys)			x	Withdrawal of specialist fertility services including IVF is likely to generate significant concern. Patients potentially affected by BMI and diabetes service criteria for bariatric surgery will also have concerns.		
	Patients, Carers and Public engagement			x	Withdrawal of specialist fertility services including IVF is likely to generate significant concern.		
	Waits for admission / Treatment		x				
	Mixed Sex breaches		x				
	Delayed Discharge		x				
	End of Life pathway		x				
	Cancelled day case operations		x				
	Waiting times for therapy services		x				
	Making every contact count		x				
INEQUALITIES OF CARE	Access to services - equality impact			x	It is difficult to tell at this stage whether this will reduce inequality or increase inequality. Most evidence from publicly funded healthcare systems shows that richer socieconomic groups are more likely receive bariatric surgery, despite having lower prevalences of obesity.		
	Variation in care provision		x				
STAFF EXPERIENCE	Workforce capability care and skills		x				
	Working practice		x				
	Staff satisfaction (e.g. FFT, annual staff survey / local surveys)		x				
	Mandatory Training compliance		x				
TARGETS / PERFORMANCE	Performance		x				
	Achievment of local, regional, national targets		x				
PROMOTING WELLBEING (in the provision of care and support)	Persons sense of personal dignity (including treatment of the individual with respect)		x				
	Persons physical and mental health and emotional wellbeing			x	Withdrawal of specialist fertility services including IVF is likely to generate significant concern. Risk of reduced physical and mental health and wellbeing with delay in bariatric surgery.		
	Abuse and neglect (safeguarding)		x				
	Personal control over day-to-day life (including over care and support provided and the way it is provided)		x				
	Opportunities for participation in work, education, training or recreation		x				
	Social and economic wellbeing			x	See above, for IVF		
	Domestic, family and personal relationships			x	See above, for IVF		
	Suitability of living accommodation		x				
	Personal contribution to society including sustainability			x	See above, for IVF		

APPENDIX 2

Castle Point and Rochford Clinical Commissioning Group
Southend Clinical Commissioning Group

EQUALITY IMPACT ASSESSMENT
(ANALYSIS OF THE EFFECTS ON EQUALITY)

NAME OF PROJECT: IN VITRO FERTILISATION and other ASSISTED CONCEPTION SERVICE RESTRICTION

DATE EIA COMPLETED: 21.11.16

ASSESSING MANAGER: LYNNE SMITH / DR MARK LIM

N.B DRAFT EIA for updating following results of public consultation

APPENDIX 2

Please refer to the Equality Impact Assessment Guidelines at each stage when completing this template.

Step 1: About your piece of work

Directorate	COMMISSIONING DIRECTORATE
Lead Manager	LYNNE SMITH
Piece of Work (hereafter referred to as "project" to be assessed	IVF SERVICE RESTRICTION
Main purpose and intended outcomes of project	RESOURCE ALLOCATION – REVIEW OF SRP
Groups whom the project should benefit or apply to, e.g., service users, CCG staff	PATIENTS REQUIRING SPECIALIST FERTILITY SERVICES
Any associated strategies, policies, guidelines, frameworks	CP&R and SOUTHEND CCGs COMMISSIONING POLICY PRIOR APPROVALS. CP&R and SOUTHEND CCGs COMMISSIONING POLICY INDIVIDUAL FUNDING REQUESTS and EXCEPTIONAL CASES APPLICATIONS
List any research or literature review evidencing that people with protected characteristics are specifically affected by this policy/process	NICE Clinical Guideline 156 (Feb 2013)

APPENDIX 2

Step 2: Initial Screening

This section assesses whether your project has any relevance to equalities.

You should score each element as follows:
3 – this area has a high relevance to equalities
2 – this area has a medium relevance to equalities
1 – this area has a low relevance to equalities
0 – this area has no relevance to equalities

Overall Impact Score:

0 points	No or Relevance	**1 – 9 points**	Low Relevance
10 – 18 points	Medium Relevance	**19 - 27 points**	High Relevance

Irrespective of the total score calculated above, the overall impact is affected by the following:
If any one or more of the equality groups has scored 2 then the overall impact is MEDIUM
If any one or more of the equality groups has scored 3 then the overall impact is HIGH.

Project (or aspect of project)	Age	Disability	Gender	Pregnancy	Marital status	Race	Sexual Orientation	Religion	Human Rights	Total Points	Overall Impact (High, Medium Low)
Revision of service restriction policy for assisted conception-access to specialist fertility services	3	1	1	0	0	0	0	0	2	7	Low

APPENDIX 2

Please identify the main issues relating to equality and diversity within your project and explain the rationale for your equality scoring:

Fertility is affected by age and NICE guidance (2013) refers to IVF treatment for women aged up to and including 39 years old, with reduced number of cycles for women aged 40-42. Suspension of NHS funding of fertility treatment for an extended period will be of greater impact to those women closest to the cut off age for eligibility to receive treatment. Men will not be affected in the same way as there is no upper age limit for their treatment. The policy is due for further review in a year's time, or possibly earlier if the financial situation allows which reduces this negative impact.
This policy impacts negatively on males and marital status as this policy, in line with the previous policy, does not support surrogacy.
The impact on human rights is considered in that neighbouring CCGs are commissioning specialist fertility services and that there will be cross boundary issues. This policy will be part of a range of service restriction polices which the CCG reviews annually, and this specialist fertility services policy will be reviewed in 2015.

APPENDIX 2

Have you identified any positive impacts upon any of the equality groups? If so, please outline

If your overall score is "none", your EIA ends here. Please email this form to the PMO Team at pmo.cpr@nhs.net or via post to Pearl House, Castle Road, Rayleigh, Essex SS6 7QF

If your score is "low", have you identified any negative impacts of your project upon equalities? Yes / No

If Yes, please outline potential impacts and changes (however small) that can be made to tackle this impact. Please record this in Section 6.

Please conduct the EIA again when you next review or change your project. Once the EIA has been approved by the Quality Team, the PMO will confirm to the Project Lead by email and diarise a six month review.

If the overall score is Medium or High, please turn over to complete your EIA.

Castle Point and Rochford Clinical Commissioning Group
Southend Clinical Commissioning Group

EQUALITY IMPACT ASSESSMENT
(ANALYSIS OF THE EFFECTS ON EQUALITY)

NAME OF PROJECT: SERVICE RESTRICTION POLICES

DATE EIA COMPLETED: 21.11.16

ASSESSING MANAGER: LYNNE SMITH / DR MARK LIM

APPENDIX 3

Please refer to the Equality Impact Assessment Guidelines at each stage when completing this template.

Step 1: About your piece of work

Directorate	COMMISSIONING DIRECTORATE
Lead Manager	LYNNE SMITH
Piece of Work (hereafter referred to as "project" to be assessed	SERVICE RESTRICTION POLICIES
Main purpose and intended outcomes of project	To reduce/eliminate any procedures which are relatively ineffective and the evidence suggests there is little or no benefit to the patient. To reduce variation in intervention rates for these procedures across the CCG To ensure consistency of access to patients to elective services To increase value for money for commissioners
Groups whom the project should benefit or apply to, e.g., service users, CCG staff	Patients: SRP aims to generate significant patient benefits by providing protection from inappropriate interventions and resultant complications. SRP also ensures consistency of access to elective services across the sector. Commissioners: The application of SRP ensures that the surgical procedures are being undertaken on patients who are most likely to benefit and therefore ensure an effective use of resources
Any associated strategies, policies, guidelines, frameworks	CP&R and Southend CCG's Commissioning Policy Prior Approvals CP&R and Southend CCG's Commissioning Policy Individual

APPENDIX 3

	Funding Requests and Exceptional Cases Application
List any research or literature review evidencing that people with protected characteristics are specifically affected by this policy/process	NHS Modernisation Agency Action on Plastic Surgery, Information for Commissioners of Plastic Surgery Services, Referrals and Policy in Plastic Surgery, (IOL) for Corneal Astigmatism Correction in Patients Undergoing Cataract Surgery. Norfolk Public Health 2015. Kessel, Line et al. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery Ophthalmology , Volume 123 , Issue 2 , 275 - 286 Robinson A. Varicose veins a2004. Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P. Injection therapy for sub-acute and chronic low-back pain. Cochrane Database of Systematic Reviews 2008, Issue 3. Iversen T, Solberg TK, Romner B, Wilsgaard T, Twisk J, Anke A, Nygaard O, Hasvold T, Ingebrigtsen T. Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: multicentre, blinded, randomised controlled trial. BMJ. 2011 Sep 13;343 Chester R, Shepstone L, Daniell H, Sweeting D, Lewis J, Jerosch-Herold C. Predicting response to physiotherapy treatment for musculoskeletal shoulder pain: a systematic review. BMC Musculoskeletal Disorders. 2013;14:203. https://www.ncbi.nlm.nih.gov/pubmed/27095553 Powell S, Kubba H, O'Brien C,Tremlett M. Paediatric obstructive sleep apnoea BMJ 2010; 340 :c1918 http://www.bmj.com/content/340/bmj.c1918 Manual of Specialised Services Commissioning 2016/7 Toric Intraocular Lens and skin complaints: how to get treatment. The Guardian. Monday 19th September. HEALTH SERVICES AND DELIVERY RESEARCH VOLUME 4 ISSUE 17 MAY 2016 ISSN 2050-4349 DOI 10.3310/hsdr04170 Costs and outcomes of increasing access to bariatric surgery for obesity: cohort study and cost-effectiveness analysis using electronic health records Martin C Gulliford, Judith Charlton, Helen P Booth, Alison Fildes, Omar Khan, Marcus Reddy, Mark Ashworth, Peter Littlejohns, A Toby Prevost and Caroline Rudisill. Ruth E. Johnson, M. Hassan Murad. Gynecomastia: Pathophysiology, Evaluation, and Management. Mayo Clin Proc. 2009 Nov; 84(11): 1010–1015. http://jpubhealth.oxfordjournals.org/content/18/2/189.long

APPENDIX 3

Step 2: Initial Screening

This section assesses whether your project has any relevance to equalities.

You should score each element as follows:
3 – this area has a high relevance to equalities
2 – this area has a medium relevance to equalities
1 – this area has a low relevance to equalities
0 – this area has no relevance to equalities

Overall Impact Score:

0 points	No or Relevance	**1 – 9 points**	Low Relevance
10 – 18 points	Medium Relevance	**19 - 27 points**	High Relevance

Irrespective of the total score calculated above, the overall impact is affected by the following:
If any one or more of the equality groups has scored 2 then the overall impact is MEDIUM
If any one or more of the equality groups has scored 3 then the overall impact is HIGH.

Project (or aspect of project)	Age	Disability	Gender	Pregnancy	Marital status	Race	Sexual Orientation	Religion	Human Rights	Total Points	Overall Impact (High, Medium Low)
Breast Procedures - reconstruction as part of treatment or prophylaxis of cancer or as part of post-trauma reconstruction surgery	0	0	2	0	0	0	0	0	0	2	**Medium**

APPENDIX 3

Facet Joint Injections: Intra-articular steroid injections into facet joints	1	0	0	0	0	0	0	0	0	0	**Low**
Spinal Cord Stimulator	0	0	0	0	0	0	0	0	0	0	**Low**
Sleep Studies	0	0	0	0	0	0	0	0	0	0	**Low**
Varicose Veins	0	0	0	0	0	0	0	0	0	0	**Low**
Gynaecomastia	0	0	1	0	0	0	0	0	0	1	**Low**
Bariatric Surgery	0	0	0	0	0	1	0	0	0	0	**Low**
Sterilisations											
Implantation of Toric Lens for Corneal Astigmatism during cataract surgery	1	0	0	0	0	0	0	0	0	0	**Low**
Total Shoulder Arthroplasty	1	0	0	0	0	0	0	0	0	0	**Low**
Hip and Spine Injections	1	0	0	0	0	0	0	0	0	0	**Low**

APPENDIX 3

Please identify the main issues relating to equality and diversity within your project and explain the rationale for your equality scoring:

Gynaecomastia –There is a gender difference BUT the surgery has low quality evidence of effectiveness hence the low score.

Hip & Spine injections – There is an age difference as the older are more likely to have back pain but low score due to age.

Toric Lens implant - There is an age difference as the older are more likely to have cataracts but low score due to age.

Bariatric Surgery – There are racial differences in the risks posed by high BMI. This will be investigated further.

Shoulder Arthroplasty - There is an age difference as the older are more likely to have shoulder pain but low score due to age.

Facet Joint Injections – There is generally an age difference

APPENDIX 3

Have you identified any positive impacts upon any of the equality groups? If so, please outline

Breast Procedures – impacts on females but procedure is offered to patients if appropriate on clinical grounds. Elective Caesarian Section - impacts on females. Also may impact on women who are unable to push during vaginal delivery due to lower spinal deformity.

APPENDIX 3

If your overall score is "none", your EIA ends here. Please email this form to the PMO Team at pmo.cpr@nhs.net or via post to Pearl House, Castle Road, Rayleigh, Essex SS6 7QF

If your score is "low", have you identified any negative impacts of your project upon equalities? Yes / No

If Yes, please outline potential impacts and changes (however small) that can be made to tackle this impact. Please record this in Section 6.

Please conduct the EIA again when you next review or change your project. Once the EIA has been approved by the Quality Team, the PMO will confirm to the Project Lead by email and diarise a six month review.

If the overall score is Medium or High, please turn over to complete your EIA.

APPENDIX 3

Step 3: Scoping

You will need to refer to the information you provided in the initial screening in step 2, and key facts and figures about the local population to complete this section. You may find it helpful to refer in detail to the questions included in the EIA Guidelines for this section.

Breast Procedures
SRP excludes breast reconstruction for anomalies other than congenital, or deformity caused by trauma or mastectomy/lumpectomy as these would be deemed purely cosmetic. The SRP affects women only.

APPENDIX 3

Step 4: Identifying Positive and Negative Impacts

Based on the evidence you have gathered in Section 3, have you identified any potential differential impact (positive or negative) for any of the equality groups?

	Positive	Negative
Age		
Disability		
Gender		
Pregnancy		
Race		
Sexual Orientation		
Marital status		
Religion		
Human Rights		

APPENDIX 3

Is the impact as a result of direct or indirect discrimination? (*refer to Guidelines for definitions of these terms)*

Yes / No (delete as applicable)

If the impact is as a result of indirect discrimination, please explain how this might be justifiable in meeting a particular aim of the project?

Who have you consulted about the positive and negative impact of the project on equality and what were their views?

APPENDIX 3

Step 5: What has been done to promote equality in your project and how will you evaluate how effective this has been?

The SRP document is available to the public on the CCG website, and goes through the stringent approval and ratification process for the CCG. Patients are aware of the process for applying for funding due to clinical exceptionality.
We will continue to monitor PALS/complaints raised as a result of funding refusal or patient unsuitable for funding. We will also monitor applications received for exceptional funding

APPENDIX 3

Step 6: What practical actions would help reduce any negative impact on the equality groups you have identified?

Issue identified	Action to be taken	Lead	Timescale
Breast Procedures			
Facet Joint Injections			
Spinal Cord Stimulators			
Sleep Studies			
Varicose Veins			
Gynaecomastia			
Bariatric Surgery	To further research racial differences	Dr Mark Lim	23.12.16
Sterilisations			
Toric Lens implantation			
Total Shoulder Arthroplasty			
Hip and Spine Injections			

You have now completed your Equality Impact Assessment

Please forward this to the PMO Team at pmo.cpr@nhs.net who will liaise with the Quality Team to ensure approval/sign off. Should the Quality Team require any further information, they will contact the Project Lead directly (and cc: PMO Team). If no further information is required the PMO Team will schedule a 6 month review and contact the Project Lead at the appropriate time.

SERVICE RESTRICTION POLICIES – APPENDIX 4

NHS Southend Clinical Commissioning Group

Submitted by: Robert Shaw, Joint Director of Acute Commissioning & Contracting

Prepared by: Dr Mark Lim

Background and Purpose of Paper

1. Earlier this summer 14 of the 15 CCGs in Essex and Anglia recently collaborated, in an exercise coordinated by Ipswich and East Suffolk CCG, to produce a list, of identified policies. The final list covered 224 clinical areas where at least one CCG had what might be classified as a service restriction.

2. Of these 224, as of May 2016, 64 did not have a like-for-like equivalent in the Service Restriction Policy shared by Basildon and Brentwood, Castle Point and Rochford, Southend and Thurrock CCGs. Of the 64, there are some which on closer inspection are related - for example, South Essex has a Dilatation and Curretage and hysteroscopy threshold, whereas Cambridgeshire have an investigation and treatment policy for Heavy Menstrual Bleeding.

3. This paper summarises the evidence considered by the Clinical Executive at Southend CCG on 10th November 2016.

1. Facet Joint Injections:

Southend CCG activity	295
Southend CCG spend	£183,925
Recommendation on changing criteria	• Intra-articular steroid injections into facet joints should **no longer** be routinely funded • Medial Branch blocks and radiofrequency denervation should only be undertaken following: (a) Biopscyhosocial assessment in the context of a multidisciplinary team (b) Completion of a self care and management plan (c) Follow up of the individual as part of a stepped management approach as part of an MDT approach
Recommendation on managing of criteria	Change from threshold to prior approval.

Key Points:

1. Facet joint injections consist, in the main, of medial branch block, intra-articular facet joint injections of steroids, and radiofrequency ablation of medial branches[1].
2. In *the British Journal of Anaesthesia*, an accompanying article[2] to British Pain Society Guidelines states that therapeutic facet joint intra-articular injections are only to be done in the context of either special arrangements for clinical governance and clinical audit or research.

3. Radiofrequency ablation typically follows diagnostic medial branch block; a randomised study[3] examined whether there should be 0, 1 or 2 diagnostic blocks prior to radiofrequency ablation; a critical appraisal of the methods raises issues acknowledged by the authors themselves and leads me to believe that a specific commissioning policy on diagnostic blocks prior to denervation would not be justifiable at this time. The British Pain Society Guidelines also contain a pathway of interventions which should be undertaken prior to this specialist intervention.
4. It should also be noted that the NHS Choices website states that back injections are not a recommended treatment of low back pain.

2. Spinal Cord Stimulators:

Southend CCG activity	8
Southend CCG spend	£29,878
Recommendation on changing criteria	• Maintain pre-requisites of: (a) Adults (b) >50mm on Visual analogue Scale (c) 6 months of appropriate conventional management (d) Successful trial of stimulation as part of the assessment • Discuss with providers the voluntary application of a more specific inclusion criteria from 'chronic pain of neuropathic origin' to 'chronic pain caused by chronic regional pain syndrome type 1 and Failed Back Surgery Syndrome.
Recommendation on managing of criteria	Maintain as prior approval

Key Points:

1. NICE Technology Appraisal 159 which states that 'Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of the assessment.'
2. The trials quoted by the review did not vindicate the use of these stimulators in all neuropathic settings, with chronic regional pain syndrome type 1 (CRPS-1), failed back surgery syndrome (SBSS) being the only three randomised controlled trials featuring a positive result.

3. Sleep Studies:

Southend CCG activity	13
Southend CCG spend	£13,114
Recommendation on changing criteria	No change
Recommendation on managing of criteria	No change (threshold)

Key Points:

Clinical Executives specifically required a discussion on under 18s. A recent paper from Queens' Hospital in Romford in the UK describes a wide range of custom and practice including restrictions in some CCGs.[4]

1. A detailed discussion on polysomnography in the under 18s can be found in the British Medical Journal[5]. The article does however note that a UK working party consensus statement endorsed by the British Association of Paediatric Otolaryngology, ENT-UK, the Association of Paediatric Anaesthetists, the Royal College of Anaesthetists, and Royal College of Paediatrics and Child Health was published in 2009.
2. The statement recognised that in the UK the decision to operate on children with sleep disordered breathing is a clinical one, based on symptom severity. As a history and examination alone cannot reliably differentiate between obstructive sleep apnoea and primary snoring, if a strategy of surgery without respiratory investigations is adopted, some children with primary snoring may have adenotonsillectomy.
3. The authors note it is not logistically possible for all snoring children to have polysomnography. It suggests a pragmatic approach is taken, and the decision to treat is based on the severity of the daytime and nocturnal symptoms reported and on the occurrence of early complications associated with obstructive sleep apnoea. These children are diagnosed with sleep disordered breathing with a suspicion of obstructive sleep apnoea.
4. From a clinical commissioning perspective, therefore, the best use of sleep studies would therefore be cases where without the sleep study there is clinical uncertainty (as well as specific anatomic circumstances such as craniofacial abnormalities or generalised illness such as failure to thrive). Criteria based on uncertainty would be difficult to formulate and audit against. Moreover, more specialised cases in Paediatric Respiratory Centres are within the remit of specialist commissioning[6]. There were 2 sleep studies aged 19 or under in the last year, and given an overall prevalence of sleep apnoea is 0.7 to 1.8% in the paediatric population, it is likely that these have been ordered appropriately.

4. Varicose Veins

Southend CCG activity	155
Southend CCG spend	£175,974
Recommendation on changing criteria	No change
Recommendation on managing of criteria	Audit existing threshold. Change to prior approval if not followed.

Key Points:

1. The existing policy funding surgery in cases of venous ulceration, recurrent superficial thrombophlebitis, bleeding (one major or two minor bleeds) and post phlebitic syndrome refractory to steroid cream.
2. It is not possible to ensure that the policy is being followed without audit if undertaken as a threshold. IT is currently prior approval.

5. Gynaecomastia

Southend CCG activity	3
Southend CCG spend	£4,710
Recommendation on changing criteria	Do not routinely fund surgical correction of gynaecomastia
Recommendation on managing of criteria	An IFR would be required to demonstrate exceptionality

Key Points:

1. The current criteria uses a classification that does not appear supported by peer-reviewed literature.
2. The evidence supporting the diagnostic approach and treatment strategies for gynaecomastia consists of expert opinion, case series, and observational studies; hence, the evidence is considered to be of low to very low quality[7].

6. Breast Procedures

Southend CCG activity	12
Southend CCG spend	£23,579
Recommendation on changing criteria	No change
Recommendation on managing of criteria	Change from Threshold to Prior Approval

1. The CCGs have had 32 **non**-cancer patients undergo these. Of the 32, 17 were for removal of prosthesis, 7 were reduction mammoplasties, 4 were mastopexies, 2 were insertion of prosthesis, 1 revision of prosthesis, 1 augmentation mammoplasty.
2. It is not proposed that the criteria change. It was originally considered that for the third reconstruction procedure onwards, this might not be funded. Only 1 of the 32 patients would have appeared to have had a third reconstruction – an unspecified breast reconstruction, insertion of prosthesis and lipofilling.
3. The policy in its present form however cannot be realistically implemented as a threshold. Auditing even a single case would require a substantial back history of the patient including General Practice records. It is recommended that the information be provided prior to surgery.

7. Bariatric Surgery

Southend CCG activity	9
Southend CCG spend	£77,000
Recommendation on changing criteria	Retention of NHS England policies on pages 8-10 in relation to treatments tried prior to surgery BMI >40 AND diabetes instead of BMI >35 with co-morbidities and BMI >40 regardless of comorbidity
Recommendation on managing of criteria	Prior Approval

Key Points:

- The numbers of current patients is small; however if the NHS England policy of BMI >40, or BMI >35 with comorbidity is adopted, the Worcestershire CCGs noted that a CCG with a population of 200,000 would have 2,500 patients in the first category – for the second category it would be over 5,500.
- There is a common misconception that bariatric surgery saves money. Both recent work by the National Institute of Health Research[8] and other studies, such as one of nearly 30,000 patients in the United States showed that a reduction in complications makes the health gained per pound **acceptable** (by NICE standards)**, but it does not cost less** – in fact over £9,000 for the procedure immediately and £15,000 over time.
- The NIHR papers notes that 'in a primary care organisation with a population of 250,000 adults aged 20–75 years, there may be 7000 people with morbid obesity. This number may be as high as 11,000 in a deprived area or as low as 4500 in an affluent area. There may be 1500 with morbid obesity and diabetes. If 1000 bariatric surgical procedures are commissioned over a period of time, the immediate financial cost will be approximately **£9.2m**.'
- Under these circumstances, retaining the original pre-surgical workup as contained within the NHS England policy is reasonable. BMI≥40 and diabetes was the most cost-effective area according to the NIHR papers (although still costing more than not having surgery).

8. Sterilisations

Southend CCG activity	4
Southend CCG spend	£2,696
Recommendation on changing criteria	No criteria
Recommendation on managing of criteria	Not applicable

[a]The cost of tubal ligations and similar was just over £27,000 across both Castle Point and Rochford and Southend CCGs in total.

Key Points:

1. An older Journal of Public Health article[9] summarised the evidence. The article noted pregnancy rates per 100 users per year: No method 85, Spermicide 21, Diaphragm 18, Condoms 12, Oral Contraceptive 3, IUD 2, Injection 0.30, Implant 0.32, Sterilisation 0.17, Vasectomy 0.04.
2. Cost per pregnancy avoided (without taking NHS costs of pregnancy into account): Spermicide £164, Diaphragm £167, Condoms £88, Oral Contraceptive £136, IUD £55, Injection £146, Implant £97, Sterilisation £22, Vasectomy £18 (based on a cost of £212 for sterilisation and £178 for vasectomy).
3. Once the costs of pregnancy are taken into account, based on 10 percent spontaneous abortion, 23 percent non-spontaneous abortion, and 67 percent live births, all the contraceptive measures are cost saving. (OPCS Codes can be found here[10]).
4. There is currently a vasectomy under general anaesthetic policy – it is not possible to check compliance other than by prior approval.

9. Specialist Fertility Services (Assisted Conception including In Vitro Fertilisation)

Southend CCG spend	£175,033
Recommendation on changing criteria	Consult on not routinely funding
Recommendation on managing of criteria	IFRs would be required to demonstrate exceptionality

Key Points:

1. NICE Clinical Guideline CG156 sets out the institute's recommendations in relation to this service area.
2. Clinical Executive does not dispute the guideline; however the affordability of implementation is the main concern.

10. Implantation of Toric Lenses for Corneal Astigmatism During Cataract Surgery

Southend CCG spend	£0
Recommendation on changing criteria	Establish new policy of do not routinely fund
Recommendation on managing of criteria	IFRs would be required to demonstrate exceptionality

1. A literature search was undertaken in 2015 by Norfolk County Council, after which they recommended that it not be routinely funded due to lack of long-term effectiveness[11]. A recent, briefer review in by Southend's public health had also been undertaken based on an individual patient request previously. Essex County Council are in the process of undertaking a review of this area as well, and the CCG will have to be mindful of this if it publishes during consultation.
2. It should be noted that a more recent systematic review[12] was undertaken adding two new studies; examination of the study characteristics however show that none of the studies have reported beyond one-year.

11. Total Shoulder Arthroplasty Policy

Castle Point and Rochford CCG activity	11
Castle Point and Rochford CCG spend	£70,891
Southend CCG activity	12
Southend CCG spend	£77,395
Recommendation on changing criteria	Introduce new policy stating that for elective cases not due to trauma, infection or neoplasm, the patient should undergo a minimum of 12 weeks' prior to surgery.
Recommendation on managing of criteria	Prior approval

Key Points:

1. There are large number of potential indications for a shoulder replacement, for which total shoulder arthroplasty appears the most cost effective. One study conducted jointly by the Universities of East Anglia and Hertfordshire[13] explicitly addressed the question as to when physiotherapy should be undertaken and if the clinician could tell whether a positive response was likely to be forthcoming. The authors noted that this was 'vital for commissioners and ensures effective and efficient use of limited resources.'
2. The authors of the review were unable to produce a meta-analysis due to the heterogeneity of the patients, but Clinical Executive has taken the overall average from the sixteen studies of 12 weeks' non-operative management as a common-sense approach to this pathway.

12. Hip and Spine Injections

Southend CCG activity	1,070
Southend CCG spend	£700,064 **(see point 1 below)**
Recommendation on changing criteria	Hips - None for the present but reserve right to early review Spinal injections – Do not routinely fund for back pain
Recommendation on managing of criteria	Hips - Audit and prior approval Spinal injections – IFR would be required to demonstrate exceptionality

1. Further examination of the codes shows that there is a single code W903 – Injection of Therapeutic Substance into Joint - which is shared by hip injections and other joints. Therapeutic lumbar epidural, sacral epidural, other epidural injections and injections around the spinal nerve root total about one quarter of the spending.
2. Hip injections are currently funded for diagnostic aid, introduction of a contrast medium as part of a hip arthrogram (and babies for hip arthrography), children and adults with inflammatory arthropathy, and investigation of infection in biological and replaced hips.
3. A Cochrane Review[14] said that there is insufficient evidence to support the use of injection therapy in subacute and chronic low-back pain. However, it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. A later randomised control trial[15], sufficiently

powered to have an 80 percent chance of detecting a difference of 10 of more in the Oswestry disability index, did not find that caudal epidural steroid was not superior to saline.

REFERENCES

[1] Patel VB, Wasserman, Imani F. Anesth Pain Med. 2015 Aug 22;5(4). Interventional Therapies for Chronic Low Back Pain: A Focused Review (Efficacy and Outcomes).

[2] J. Lee et al. Br. J. Anaesth. 2013;111:112-120. http://bja.oxfordjournals.org/content/111/1/112.full.pdf

[3] Cohen SP, Williams KA, Kurihara C, et al. Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation. Anesthesiology 2010;113:395-405. http://anesthesiology.pubs.asahq.org/article.aspx?articleid=1933210

[4] https://www.ncbi.nlm.nih.gov/pubmed/27095553

[5] Powell S, Kubba H, O'Brien C,Tremlett M. Paediatric obstructive sleep apnoea BMJ 2010; 340 :c1918 http://www.bmj.com/content/340/bmj.c1918

[6] Manual of Specialised Services Commissioning 2016/7

[7] Ruth E. Johnson, M. Hassan Murad. Gynecomastia: Pathophysiology, Evaluation, and Management. Mayo Clin Proc. 2009 Nov; 84(11): 1010–1015.

[8] HEALTH SERVICES AND DELIVERY RESEARCH VOLUME 4 ISSUE 17 MAY 2016 ISSN 2050-4349 DOI 10.3310/hsdr04170 Costs and outcomes of increasing access to bariatric surgery for obesity: cohort study and cost-effectiveness analysis using electronic health records Martin C Gulliford, Judith Charlton, Helen P Booth, Alison Fildes, Omar Khan, Marcus Reddy, Mark Ashworth, Peter Littlejohns, A Toby Prevost and Caroline Rudisill.

[9] http://jpubhealth.oxfordjournals.org/content/18/2/189.long

[10] http://www.cambridgeshireandpeterboroughccg.nhs.uk/downloads/CATCH/Sterilisation%20Guidelines%20OCT%202012.pdf

[11] Toric Intraocular Lenses (IOL) for Corneal Astigmatism Correction in Patients Undergoing Cataract Surgery. Norfolk Public Health 2015.

[12] Kessel, Line et al. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery Ophthalmology , Volume 123 , Issue 2 , 275 - 286

[13] Chester R, Shepstone L, Daniell H, Sweeting D, Lewis J, Jerosch-Herold C. Predicting response to physiotherapy treatment for musculoskeletal shoulder pain: a systematic review. BMC Musculoskeletal Disorders. 2013;14:203.

[14] Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low-back pain. Cochrane Database of Systematic Reviews 2008, Issue 3.

[15] Iversen T, Solberg TK, Romner B, Wilsgaard T, Twisk J, Anke A, Nygaard O, Hasvold T, Ingebrigtsen T. Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: multicentre, blinded, randomised controlled trial. BMJ. 2011 Sep 13;343