Medicines Excluded from National Tariff Payment System: 2017-19

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<tbody>
<tr>
<td>Version</td>
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<tr>
<td>Approved by</td>
<td>Surrey &amp; North West Sussex Prescribing Clinical Network and internally through the Guildford &amp; Waverley CCG Medicines Optimisation Group</td>
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<td>Name of author/originator</td>
<td>Sarah Watkin, Associate Director of Pharmaceutical Commissioning, Surrey Downs CCG</td>
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<td>Vicky Stobbart, Managing Director, GWCCG</td>
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<tr>
<td>Date of approval</td>
<td>Prescribing Clinical Network on 4\textsuperscript{th} April 2018.</td>
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<td>It was agreed at the CCG through the Medicines Optimisation Group on 12\textsuperscript{th} June 2018.</td>
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<td>Date of last review</td>
<td>It is reviewed annually for changes to the drug list and most recently updated in March 2018.</td>
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<td>This policy has previously been included into provider contracts; however it is now being made available on the CCG website.</td>
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<tr>
<td>Review to be completed by</td>
<td>Sarah Watkin, Associate Director of Pharmaceutical Commissioning, Surrey Downs CCG by 31/03/19.</td>
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### Version control sheet

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<thead>
<tr>
<th>Version</th>
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<td>Final version for 2017-2019</td>
<td>03/08/18</td>
<td>Sarah Watkin, Associate Director Pharmaceutical Commissioning – Surrey Downs CCG</td>
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Arrangements for medicines excluded from national tariff payment system: 2017-19

1. **Introduction**
   1.1. The tariff payment system is based on nationally calculated averages. It is expected that against the tariff, providers will incur a deficit or surplus in the course of providing a care event.
   1.2. A number of high cost medicines, devices, procedures and products are excluded from the scope of the national tariff payment system and are published by NHS Improvement. These medicines will either be:
      - commissioned by specialised commissioning which is part of NHS England; OR
      - commissioned by the Clinical Commissioning Groups (CCGs) if prescribed within approved criteria
   1.3. This document provides a statement of the CCG’s commissioning arrangements for managing these medicine exclusions which are the responsibility of the CCGs for 2017/18 and 2018/19.

2. **General Principles**
   2.1. All new and existing medicines and technologies will be provided within the scope of National Tariff guidance unless:
      - explicitly excluded through the National Tariff exclusions list e.g. excluded high cost medicines, devices or as part of excluded services; OR
      - through local arrangements agreed with the commissioners
   2.2. NHS Improvement and NHS England guidance on excluded medicines will be followed. Any new medicines identified as excluded, within the financial year may be treated as exclusions, but this will be dependent on the NHS Improvement/NHS England high cost drug list and specialised commissioning (NHSE) drug list
   2.3. Where Best Practice Tariffs (BPTs) are in place, medicines are considered to be included in tariff unless listed as specific exclusions on National Tariff Exclusions list OR within the National Tariff Guidance.
   2.4. Those medicines subject to specialised commissioning by NHS England are not covered by this document.

3. **Funding**
   3.1. These arrangements relate to tariff excluded medicines (and insulin pumps) that are commissioned by CCGs. The CCG will provide a list specifying details of the CCG’s requirements for excluded medicines. It will include both NHS Improvement and specialised commissioning (NHSE) drug lists for information.
   3.2. There may be medicines listed that are the commissioning responsibility for CCGs but a commissioned service with a provider may not be in place and where this is the case an annotation will be made next to the medicine.
   3.3. For patients starting new interventions the CCG:
      - Will fund excluded medicines that are used in accordance with NICE technological appraisal recommendations or as detailed in the CCG medicine list. Baseline data must be recorded clearly in
the patient’s notes in order to enable post payment verification audits in NHS providers (with prior agreement) to assess whether excluded medicines are being used in accordance with agreed commissioning criteria.

- ALL other excluded medicines i.e. licensed but not yet subject to NICE review; unlicensed; or new high cost medicines that are in-year developments, will only be funded following the agreement of an in year service development after consideration by and support of the Prescribing Clinical Network (PCN) (details of how to take this forward can be obtained by contacting the team at highcost.drugs@nhs.net) OR for an individual patient in exceptional clinical circumstances / rarity request (see CCG Operating Policy for Dealing with Individual Funding Requests).

3.4. The CCG will not routinely commission for use, a medicine under review by NICE, for which no appraisal or guideline has been published, regardless of the existence of a zero-cost scheme (unless there is a local written agreement in place between CCG and NHS Trust). Any NHS Trust signing up to such an offer does so at their own risk, understanding that where the final published guidance does not recommend the therapy, or where the individual patient does not meet the NICE recommended criteria for use, the CCG would in no way be bound to fund on-going treatment. Where a medicine receives a positive appraisal and recommendation for use by NICE, local procedures for adoption of NICE recommended medicines must be followed.

3.5. The embedded document provides details of funding arrangements for each excluded medicine. There may be some minor variations between Trusts, based on local negotiations.


3.6. Where NHS England transfer responsibility for funding of an excluded medicine (or device) to CCGs in year, a contract variation will be required. Before the variation can take effect, the CCG will require assurance from providers regarding governance and operational arrangements in order to ensure best clinical and operational practices are in place. Until such time as the CCG is suitably assured and a change note enacted, the medicines list (excluded medicines funding expectations for individual medicines) as contracted at signing will continue to apply.

4. Application process

4.1. Tick Box Forms

4.1.1 The CCG has developed a series of standard tick box forms for notification of initiation of excluded medicines in line with national or local funding criteria and communication of continuation.

4.1.2 Forms must be submitted to electronically via the web-based database https://www.blueteq-secure.co.uk/trust/. The CCG will not accept scanned forms, data embedded into an email or emails from a non nhs.net account. The patient must meet ALL pre-determined criteria for funding to be approved.
4.2. Treatment Initiation

4.2.1 Notification forms must be received by the CCG before the first invoice for that treatment is made to the CCG.

4.2.2 Treatment should not be withheld, whilst waiting for the CCG to respond to the treatment request on the Bluteq database, if the patient meets all the criteria for funding, treatment should commence without delays for the patient.

4.2.3 All patients will be required to confirm that consent has been given for confidential and/or sensitive information to be passed to the CCG for processing a funding request and for validating subsequent invoices. Consent is only required ONCE at the point of the initial funding request.

4.2.4 The provider should ensure that criteria for stopping treatment are discussed with the patient before a medicine is initiated. The notes should reflect this discussion and that the patient has agreed to these conditions.

4.3. Treatment continuation

4.3.1 Consultants and their teams should be encouraged to use the Bluteq system as a means of communication with the pharmaceutical commissioning team. The team will use Bluteq to communicate with provider teams requesting clarification where funding criteria is not clear. This communication will be either via email directly from Bluteq or will be marked as a comment on the patient’s record on the database. The provider will be notified that a comment has been made on the patient’s record in all cases.

4.3.2 Consultants and their team should provide objective evidence of response to treatments (if required) to establish whether or not a patient has responded to treatment in line with the criteria included in NICE TAs/locally commissioned guidelines. If it is not possible to provide objective data the CCG may consider subjective data. Continuation forms are available on Bluteq for this purpose.

4.3.3 The CCG will expect that information in relation to patient response will be received within 3 months of the follow up date (marked on the database), using the Bluteq continuation forms. After 3 months if no information has been received the CCG will assume that treatment has been discontinued and funding is no longer required. The Bluteq database will be marked as ‘funding suspended’ at this point. Any treatment provided beyond this point will be from within the Trust’s resources.

4.3.4 Where a patient has shown inadequate or no response (against NICE TA criteria/locally commissioned guidelines), the CCG will notify the provider that further funding has been declined.

4.3.5 Trusts may appeal a decision to withdraw funding. The appeal should be submitted in writing or via email to the pharmaceutical commissioning team and be backed up by patient specific data (this should include subjective and objective data summarising the patient’s current clinical status).

○ Email: highcost.drugs@nhs.net OR
4.4. Individual Funding Requests

4.4.1 Where a medicine is considered as an excluded medicine and there is no national or local guidance available, providers can apply for funding via the Individual Funding Request route, please refer to the Operating Policy for Dealing with Individual Funding Requests for information on how to apply for funding. Where funding is approved for an initial time period, information in relation to patient response should be received within 3 months of the last treatment.

4.4.2 Where funding is being requested via the IFR process the providers should ensure that all sections of the IFR form are completed and that any supporting data is forwarded with the request. Requests requiring consideration more rapidly than above should be clearly marked ‘urgent’ and state the reason(s) as to why they are urgent. Where it is not clinically safe to wait for a funding decision, the Trust may start the treatment and forward the completed application form to at the earliest possible opportunity.

4.5. Responsibilities (Commissioner and Provider)

4.5.1 Surrey Downs CCG pharmaceutical commissioning team will ensure efficient processing of all applications for funding and will work to the following standards:

- **Notification**: Provider must submit a tick box form before the first invoice for that treatment is made to the CCG. The Blueteq database will be annotated with a funding decision (Approval, Decline OR request for further information) within 5 working days of receiving full information for 95% of requests received.

- **Individual Funding Requests (prior approval)**: For more details please refer to the CCG Operating Policy for Dealing with Individual Funding Requests.

4.5.2 Trusts are also asked to note that this standard applies from the point when the CCG pharmaceutical commissioning team is in receipt of full information (and supporting references where applicable) to support the funding request. Both parties will strive to achieve these requirements and targets and will monitor performance against the defined standards.

5. Invoices

5.1. Medicine charges must be for the medicine only and at acquisition cost or at nationally/locally procured/contracted prices, whichever is lower. There will be no additional charges automatically added to medicine prices without prior discussion and explicit agreement with commissioners and in accordance with National Tariff rules.

5.2. Invoices should be submitted **every month** and **a minimum supporting data set** must be sent (in line with national timescales) to the Data Services for Commissioning Regional Offices (DSCRO) for processing.
5.3. Providers must provide the same data set to the CCG pharmaceutical commissioning team as the NHS England data set: (Please note that the team processing the SLAM have ASH status).
   - NHS number
   - Drug name (both generic and brand (statement of brand name for biosimilar products as recommended as good practice by MHRA).
   - Quantity of drug issued e.g. 4 x 50mg prefilled injection
   - Date of issue
   - Acquisition cost of drug (CCG can request invoice for verification)
   - Speciality or clinical department
   - Indication (preferred but not mandatory if speciality or clinical department already stated)

Please note any additional pre-agreed charges will be listed on a separate line to the related medicine or device within the invoice.

5.4. A full data set must be provided with all invoices to enable payment. If this information is not available the CCG will challenge the invoice through the CCG contracting teams.

5.5. Where CCG records show no current approval for an excluded medicine, the invoice will not be paid until such time that an application is made by the provider via Blueteq. Only future invoices will be paid. Invoices for retrospective treatment will not normally be paid unless in exceptional circumstances.

5.6. The same will be applied to patients for whom funding has expired and the Blueteq database marked as ‘funding suspended’.

6. Management of challenges for medicines excluded from tariff

6.1. Providers and CCGs must adhere to an agreed timetable for reporting of charges through the SLAM, issuing of and responding to challenges and queries.

6.2. CCGs will review the charges and issue challenges in anticipation of receiving a credit from the Provider. Challenges may include (this is not an exhaustive list):
   - Full requirement of minimum database not given that is needed to validate charge
   - Charge greater than expected
   - Multiple charges for same patient
   - Brand not provided (e.g. Brand of Biosimilar (MHRA recommendation))
   - Homecare charges (not agreed with host commissioner)
   - Notification of initiation not received by responsible commissioner
   - Invoice for medicine that is not excluded
   - Medicine funded by NHS England not CCG

6.3. Providers and CCGs will work to closedown outstanding claims on a quarterly basis.

7. Homecare

7.1. If providing medicines to patients through homecare arrangements, Providers should be able to demonstrate that they are working towards compliance with policy or guidance published in response to the findings.
of the Hackett Report on homecare medicines including professional standards issued by the Royal Pharmaceutical Society of Great Britain.

8. **Clinical Trials and compassionate funding**

8.1. Funding arrangements for the period following completion of a clinical trial must be agreed with the commissioners prior to the trial commencing. It should be noted that the CCG does not normally fund medicines following the completion of a clinical trial or withdrawal of compassionate funding by a pharmaceutical company. Ethically, patients participating in a clinical trial must be made aware that there is no guarantee that the medicine will be continued at the end of the trial, irrespective of the results. (The CCG has adopted SEC PRC PR2010-02 in relation to NHS pick up of trial funding). Please note that where this document refers to historical PCTs, this should now apply to CCGs. [Link](http://www.guildfordandwaverleyccg.nhs.uk/website/X09413/files/100601-PR2010-02_NHS_Pickup_of_Trial_Funding_SECPRC.pdf)

9. **Patients changing responsible commissioner**

9.1. The CCG has adopted SEC PRC PR2011-01 in relation to patients changing responsible commissioner). Please note that where this document refers to historical PCTs, this should now apply to CCGs. [Link](http://www.guildfordandwaverleyccg.nhs.uk/website/X09413/files/110201-PR2011-01_Patients_Changing_Responsible_Commissioner_SECPRC.pdf)

10. **Private patients**

10.1. If NHS funding is being requested for excluded medicines, the patient should be referred into the appropriate NHS services in order that an application for funding can be made to the CCG in the usual way as for NHS patients. NHS patients who have previously received private treatment will not be given an unfair advantage over other NHS patients.

11. **Co-payment**

11.1. Guidance on NHS patients who wish to pay for additional private care was published on 23rd March 2009, by the Department of Health. NHS organisations should not withdraw NHS care simply because a patient chooses to buy additional private care.

11.2. Prior to initiating a referral for co-payment, the consultant should exhaust all reasonable avenues for securing NHS funding before suggesting a patient’s only option is to pay for care privately. Prior to starting co-payment treatment patients must be informed:

- That the additional treatment and any associated costs are not being funded by the NHS
- Of the associated costs from the private care provider
- That if they become unable to fund their treatment (i.e. ‘run out of money’) that the treatment will stop. The NHS will not provide treatment.
- That if the NHS decided to fund this treatment in the future, the NHS would not normally refund the cost of treatment already given privately.
See individual Trusts’ operational policies for co-payment

12. **Pass Through**

12.1. Pass-through payments are additional payments made to Providers over and above the relevant tariff reimbursement for use of a particular medicine (which is not included in the excluded medicine list) which could not have been expected when the price of the HRG was established. Primarily this applies to new medicines but could also apply to medicines that are not new but are of disproportionate cost relative to the HRG tariff.

12.2. DH criteria for pass-through payments:
- Delivered in a limited number of centres and
- Of disproportionate cost relative to the HRG tariff
- And for new use for existing medicines, also coded to a relatively high volume HRG where the activity within the HRG is heterogeneous in nature.

12.3. The CCG’s definition of disproportionality in this context is:
- For an individual medicine that the additional / incremental cost Full Year Effect (FYE) per patient is no less than £2,000 over the existing therapy that is within tariff.
- The Part Year Effect of the cost pressure to any individual provider of the medicines at purchase price (including VAT where applicable) is greater than £50,000, based on the estimated number of patients put forward for this service development.

12.4. The CCG will review the cost effectiveness evidence (including NICE) prior to agreeing a pass-through payment. The price attached to the pass-through payment relates only to the additional costs associated directly with the medicine and its use relative to the cost of alternative treatment. Pass-through payments will be reviewed by the CCG before the start of each financial year to see if the usage of the medicine is to be included in the relevant tariff reimbursement.

12.5. Providers should apply to the CCG for pass-through payment for a new medicine by submitting a business case for consideration by the Prescribing Clinical Network (unless the medicine is NICE approved / defined within specialist commissioning arrangements and a tick box form has been produced and a pass-through payment agreed through contracting). Decisions made by the Prescribing Clinical Network will be ratified by the CCG’s board and once ratified a pass-through payment will be agreed through contracting.
**Glossary:**

- **Service Development** – Clinical need identified for a group of patients where a business case is required to provide the service. Contact the pharmaceutical commissioning team at NHS Surrey Downs CCG who will be able to discuss the process and a way forward at [highcost.drugs@nhs.net](mailto:highcost.drugs@nhs.net)
- **NICE** – National Institute for Health & Care Excellence
- **TA** – Technology Appraisal
- **SLAM** – Service Level Agreement
- **ASH** – Accredited Safe Haven
- **IFR** – Individual Funding Request