2020-21 South West London (SWL) Commissioning Principles for PbR Excluded Drugs / Devices

Commissioning agreement

1) The South West London Clinical Commissioning Group (SWL CCG) will commission all Payment by Results (PbR) excluded drugs/devices as detailed in Appendix 1 in line with NICE Technology Appraisals (TA) and/or agreed SWL commissioning policies. The SWL CCG will not commission or pay for drugs/devices for which NHS England is the responsible commissioner.

2) NICE approved drugs/devices recommended by a NICE TA that are excluded from tariff will be funded within 90 days of its publication. Providers are expected to meet the requirements of NICE TAs and be able to demonstrate compliance through submission of funding applications via Blueteq (see item 16 below).

3) The CCG will disinvest in technologies which may be effective, but which have been superseded by other more cost-effective ones, as recommended by NICE. The SWL Medicines Optimisation Group will advise the CCG on the appropriate areas for disinvestment.

4) The CCG will fund all PbR Excluded drugs/devices only where requests comply with the SWL framework as listed in Appendix 1 and below.

5) All other Excluded drugs/devices will only be funded if:
   - There is ***a specified and documented*** local agreement. Where a local agreement has been made with the CCG, a copy of this must be submitted for assessment as to whether it applies and therefore warrants payment by the patient's CCG. This will then be captured in the "SWL CCG Commissioned PbR excluded drug/device list 2020/21" (Appendix 1).
   - It is approved as an Individual Funding Request (IFR) where there is evidence that the patient has clinically exceptional circumstances in comparison with other patients with the same condition presenting at the same stage of the disease. However, where the intervention relates to a cohort, a business case will be required so that a policy can be developed which is usually for the following financial year.

6) Where drugs and devices are used outside of CCG commissioned services any consequential costs that are incurred will not be funded. This includes the costs associated with the entire treatment.

7) Non-excluded drugs/devices prescribed concurrently with the excluded drugs/devices are not chargeable as these are covered within national tariff.

8) Excluded drugs/devices recommended within a NICE Interventional Procedures Guidance (IPG) and/or guideline will not be routinely funded unless endorsed by a SWL commissioning policy.

9) A contract plan for excluded drugs and devices will normally be set on an annual basis. This will be informed by the provider's assessment of need through horizon scanning. It is the responsibility of providers to inform commissioners of any anticipated cost pressures, including those relating to NICE TAs within prioritisation round timescales. The provider is expected to horizon scan implications of NICE approved technologies, those in development and other developments and set out financial and service implications and the pathway they are proposing to use. New excluded drugs and devices will not be funded in-year unless approved by a NICE TA or previously identified and planned for within the prioritisation round.

10) **Private patients:** If NHS funding is being requested for excluded drugs or devices for patients seen privately, the patient should be referred into the appropriate NHS service 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.

Financial assumptions

11) National tariff pay and price adjustments are not automatically applied to drugs and devices excluded from tariff i.e. SWL CCG will pay actual costs (see item 12). These costs are also omitted from tariff efficiency deflator arrangements. The CCG is committed to constantly adopting the national rules as published in all contracts and therefore will be omitting excluded drugs and device budgets from the contract value to which CQUIN applies for all SWL CCG contracts in 2020/21 and onwards.

12) The SWL CCG will only pay the actual cost of the drug/device at which the provider procured the treatment (including any LPP discounts, Patient Access Scheme discounts, other discounts or retrospective rebates), in line with PbR guidance. No additional charges above cost will be accepted. Any additional (administrative or other) charges applied to drugs or devices will not be honoured unless specifically identified in 2020/21 PbR guidelines or explicitly agreed with the SWL CCG **and** specifically agreed within the contract (see also Appendix 2 and 3). The same will apply to drugs/devices which have been approved following submission to the IFR panel of the relevant CCG. The CCG will reserve the right to audit provider costs to demonstrate compliance with this term.

13) The SWL CCG commissions treatment pathways and charges in line with the charges considered by the NICE costing templates. NICE costing templates include information on activity charges used to cost the full treatment pathway (including cost of the drug/device, price of activity associated with the drug/device, price of activity when patient is followed up). The provider is expected to implement these charges (or less) unless specifically agreed otherwise.

14) In line with the DoH 'Better Procurement, Better Care, Better Value' strategy, the SWL CCG request that providers help identify proposals to further increase quality and cost-effectiveness of using CCG commissioned PbR excluded high cost drugs/devices. Any proposals on sharing benefits/gains will be considered in line with NHS England's 'Principles for sharing the benefits associated with more efficient use of medicines not reimbursed through national prices' and other relevant national and local guidance (e.g. from NHS England Specialised Commissioning Medicines Optimisation Clinical Reference Group (CRG)). (See appendix 2 for 2020/21 SWL arrangements for the introduction of biosimilars).

15) PbR excluded drugs which are offered at zero or discounted cost or with alternative advantageous pricing arrangement to the NHS e.g. prior to or following the publication of a NICE TA, should not be accepted by providers without the explicit agreement of the host commissioner. The CCG will not fund ongoing treatment following publication of a NICE TA if the patient does not meet NICE criteria and if treatment was started without prior agreement of the commissioner. The same applies to drugs that may have been started in preference to other drugs, due to a temporary zero, discounted or alternative advantageous price, if this was not explicitly agreed with the host commissioner. SWL adopt the "Free of Charge (FOC) Medicines Schemes" advice ratified by Regional Medicines Optimisation Committee for adoption as local policy (v1.0 July 2018).

Approval process for drugs and devices listed in Appendix 1. Refer to Effective Commissioning Initiative (ECI) policy for other PbR excluded devices and procedures.

16) There are four ways in which PbR drug/device exclusions are processed in SWL:

I. Tick box forms (TBFs): TBFs aim to ensure that drugs/devices are used in line with NICE or other national/locally agreed guidelines. Completed TBFs have to be submitted via Blueteq unless advised otherwise by the CCG or organisation that acts on the CCG's behalf in accordance with Appendix 1 either:

- Prior to starting drug/device therapy for the CCG to give approval first (**prior approval**) or
- Within <u>two weeks</u> of the treatment being started (**notification**) – this applies to the majority.

For either scenario, the CCG will provide a response within 10 working days of receiving full information and are not obliged to pay for treatment already started which does not meet agreed criteria or when not all requested information is provided.

The TBF or equivalent, must be fully completed and submitted by providers (along with any supporting data if this is requested) and should contain a minimum dataset consisting of:

- Patient consent to share patient identifiable data for the purpose of processing the funding requests and subsequent invoice validation
- NHS number
- Hospital number
- Year of birth
- GP name
- Practice code and post code
- Requesting consultant
- Contact details
- Patient NHS status confirmation
- Patient's weight (where applicable)
- Proposed dose and frequency
- Confirmation of EACH cited NICE criteria or criteria defined in other national or locally agreed guidelines
- Drug/device acquisition cost that will match invoice amount

Drug/device acquisition cost stated on the TBF must be:

- London Procurement Partnership (LPP) list price or
- National discount, rebates or other Patient Access Scheme (PAS) agreed as part of a NICE TA review or
- Local negotiated contract price / list price plus VAT (whichever applies), where not on LPP list or
- Price agreed as part of local arrangement for the introduction of biosimilars (see appendix 2) or other local agreements (see appendix 3).

and

- Equal actual drug/device acquisition cost to be paid by the CCG (administration costs and prescribing costs of aligned therapies should not be added and will not be paid for as a PbR exclusion (see 11 and 12 above)

The CCG will usually approve to fund a course of treatment or treatment for a specified length as specified on the TBF. If the provider wishes to continue treatment beyond the (initially) approved funding period, the provider:

- Must apply for **continuation of funding** via Blueteq unless advised otherwise by the CCG or organisation that acts on the CCG's behalf at the defined intervals specified on the TBF (usually by completing "Request for continuation of funding for PbR Exclusion" proforma).
- Should re-confirm patient's compliance with defined clinical criteria
- Should provide updated drug/device acquisition costs (as above)

See Blueteq for tick box forms in use.

II. PbR excluded drugs/devices without TBF for use in defined indications only: Trusts can use these PbR excluded drugs/devices for specified indications. These are not managed through TBF, but providers are required to submit the indication for use on the invoice. Providers can expect payment if they use these PbR excluded drugs for specified indications as listed in Appendix 1.

III. Local agreement: In some instances, it is appropriate to have a local agreement for certain drugs/devices (see item 5 above). However, the CCG may still request details as defined in I and II above to verify that the patient meets agreed criteria. For example, this may be applicable where one provider has a block contract with one borough of the CCG but not with other boroughs of the CCG where activity is unpredictable or low.

IV. IFR: PbR excluded drugs/devices which do not fall under I, II or III above are not usually funded unless approved following submission of an IFR request.

17) In order to secure funding for PbR excluded drugs / devices or drugs not routinely commissioned, TBFs and Individual Funding Request (IFR) forms should be screened by suitably trained provider pharmacy staff before submission. This is to ensure that only valid applications are submitted that meet all contractual requirements for PbR excluded drugs/devices or the IFR policy (for IFR

applications) and that applications are not submitted where this is not the case and thereby avoid undue delays.

18) If a patient transfers from a CCG outside SWL to the SWL CCG, but remains a patient of the same provider, the provider should notify the CCG/CSU via Blueteq as described in point 15 above supplemented by any previous funding application and subsequent approval from the former CCG to explain any deviation due to differing pathways.

19) In cases where the commissioning responsibility changes from NHS England to CCGs, either because the drug has been reallocated or the patient has reached adulthood, a new initial application should be submitted on Blueteq as appropriate.

20) Patients, who have been receiving PbR excluded drugs/devices for a while without any record of approval, require submission of an initial TBF (via Blueteq) with data reflecting the situation prior to starting treatment. If treatment has been given beyond the initial approval period as specified on the application form, the provider should also apply for a re-approval at the same time in order to secure continued funding.
This also applies to the following:
    - Patient was previously registered with a GP in a different CCG (see also 18)
    - Inter-hospital transfers
    - Transfer from outside England

21) Patients without any record of approval, who were started on PbR-excluded drugs/devices prior to NICE guidance or implementation of TBFs or where the required information to demonstrate NICE compliance is not available, will be reviewed on an individual basis by the CCG/CSU. For these legacy patients, the provider is required to provide available data in a timely and comprehensive manner as advised by the CCG/CSU team in order to secure future reimbursement. For inter-hospital transfers and transfers from outside England, the receiving provider is expected to make reasonable attempts to obtain required data to demonstrate NICE compliance. If data is not available, this should be evidenced by a letter from the discharging provider that baseline data are not available. Commissioners intend to work with providers to agree a more efficient process in resolving repeat challenges for patients without record of approval.

22) For insulin pumps and continuous glucose monitors, the invoice should reflect the price agreed with SWL commissioners, as part of the London Procurement Partnership framework.

23) Information provided to request (initial and ongoing) funding for PbR excluded high cost drugs/devices (usually via Blueteq) is part of and should mirror patient clinical records.
As part of the quarterly review process, the CCG reserves the right to visit the provider on an agreed audit day to jointly carry out post verification audits comparing submitted data for requesting funding for PbR excluded high cost drugs/devices versus patient's clinical records. This will be on an ad hoc basis (maximum 2 audits per provider per year). Data will have to be extracted from patient's notes by provider staff on the audit day on a pre-set representative sample of patients. This information will be checked by CCG/CSU staff against data submitted to the CCG/CSU when requesting funding (with honorary contracts in place to cover patient confidentiality regulations).
If the sample of the audit identifies that there are discrepancies, an appropriate action plan will be agreed between the provider and the CCG. If the discrepancies are showing that funding for PbR excluded drug/device applications are not filled in honestly, this may ultimately result in applying the % breach identified in the sample across the total high cost drug/device charges for that year and a rebate payment will be expected from the provider.

Invoice Validation and Payment

24) Excluded drugs/devices will be payable where:

I. Exclusions related to PbR tariff comply with the principles outlined in this document and Appendix 1.

II. Drugs/devices related to non-PbR tariff services will be subject to local prices. Funding will be dependent on a provider demonstrating a reduction in local prices resulting from removal of drug/device costs. This will be determined by local agreement.

25) All PbR excluded drugs/devices (excluding those that are subject to IFR) are to be paid via monthly main contract invoices and over and under performance main contract invoices and must be reported via monthly SLAM. PbR excluded drugs/devices invoices submitted via Oracle will not be processed. This also applies to any agreed gainshare payments and homecare fees, which must be reported via monthly SLAM as specified in the agreement, in such a way that the gainshare payment or homecare fee can be clearly identified and segregated from the actual cost of the medicine/device.
Drugs/devices which are subject to IFR approval must be invoiced monthly separately from the main contract and should not be submitted via SLAM.

26) Providers should have robust systems to ensure SLAM and SLAM-PLD charges for drugs and devices are submitted in a timely manner as follows:
    - Within 2 months of issuing medication when supplied by the provider
    - Within 3 months of issuing medication when supplied by a third party (e.g. home care)

    Delayed submissions within one financial year require an explanation on the SLAM-PLD. Any undue delays in submitting invoices which would cross over into the next financial year require prior notification to the CCG/CSU Finance Lead/Contract Lead and can only be submitted with prior agreement from CSU/CCG Finance/Contract Lead. In this scenario any financial year-end deals and settlements with the provider will be taken into account.

27) The patient backing (or supporting) data for all PbR excluded drugs/devices must be submitted monthly in line with flex and freeze dates. Patient backing data must contain, as the minimum data set, the following mandatory fields:
    - NHS number
    - Hospital number
    - Person birth date
    - Age
    - Gender
    - Drug/device name
        - including brand name if different brands are available. This is e.g. applicable to somatropin (e.g. Genotropin®, Norditropin®, Omnitrope®), botulinum toxins (e.g. Botox®, Dysport® or Xeomin®) and biosimilar versions of biologic drugs (e.g. Infliximab (Remicade® or Remsima®), etanercept (e.g. Enbrel® or Benepali®), adalimumab (e.g. Humira® or Hulio®)
        - including formulation where the same drug can be administered via different routes. This is e.g. applicable to tocilizumab IV or tocilizumab SC and abatacept IV or abatacept SC
        - and state if supplied via homecare
    - Drug strength
    - Quantity supplied
    - Therapeutic indication including:
        - if treatment is for eyes, state which eye (left or right), e.g. wet-AMD- left eye
    - Reporting month (billing month)
    - Organisation code (code of commissioner)
    - Total cost for current claim (note: any gain-share to be retained by the provider needs to be clearly separated from the actual cost of the drug/device by stating the price of the medicine, and the gain-share element as separate lines, e.g.
        - Infliximab (Flixabi®): £cost of Flixabi®
        - Infliximab (Flixabi®)- gainshare: £gainshare charge

    Trust may use the Drugs Taxonomy and Monthly Dataset Specification defined by NHS England, provided that the mandatory minimum dataset defined above is included, even if this is not mandated by NHS England.

28) Any invoices submitted by 3rd party suppliers (e.g. homecare companies) will not be paid and will be redirected to the relevant provider.

29) In recognition of the complexity of challenges and their subsequent responses, the National timetable does not appear appropriate for raising and responding to challenges for excluded drugs and devices. It is therefore proposed that:

- The provider will submit the patient level data in line with the National timetable.
- The CCG will process attribution challenges in line with the National timetable.
- The CCG will submit patient level challenges for PbR excluded drugs/devices 14 calendar days after the national timetable and include the challenge summary in the provider challenge letter of the next month.
- Providers are required to respond to attribution challenges within the National timetable.
- Providers are required to respond to patient level challenges for PbR excluded drugs/devices for that particular month within 14 calendar days of the challenge submission and clearly indicate whether each challenge is accepted or rejected and a detailed reason in their response to the CCG (any investigations should be concluded by then).
- Subsequent challenge communication should normally be responded to within 10 calendar days (14 calendar days during Christmas and Easter holiday period).

30) Following a successful challenge by a CCG, the provider is required to adjust their SLAM at the earliest opportunity within 2 months and within the same financial year.

31) The SWL CCG will not fund treatments if any of the above criteria are not met and will not pay retrospective funding requests. Invoices for PbR excluded drugs/devices without notification and funding approval will not be paid until such time that an application is made in which case only future (not retrospective) invoices will be paid. The same applies to patients for whom initial or subsequent funding has expired. Any occasional omissions of notifications which are subsequently provided within the timetable for challenge responses for that particular month will be paid if all criteria are met.

32) The funding CCG reserves the right to post-payment validation of any charged high cost drugs/devices with the full co-operation of the provider.

Appendix 1: SWL CCG commissioned PbR excluded drug/device list

Appendix 2: SWL agreement for biosimilars

Appendix 3: SWL agreement for PbR excluded drugs delivered via homecare

Appendix 4: SWL agreement for insulin pumps

Appendix 5: SWL agreement for continuous glucose monitors

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