

Vaccinations not covered under Section 7a:

who pays?

RECENT CHANGES TO COMMISSIONING

The NHS has undergone profound changes in the way it commissions services with the introduction of the Health and Social Care Act in 2012, resulting in NHS England (NHSE) area teams taking on responsibility for commissioning immunisation programmes in collaboration with the Department of Health (DH) and Public Health England (PHE).¹ NHSE is now responsible for the routine commissioning of national screening and immunisation programmes under the terms of the Section 7a agreement (S7a).

Since April 2013, national population-based screening and immunisation programmes are provided under the terms of S7a. This is negotiated with the Secretary of State for Health (who allocates the funds) and NHSE (who commission the services) under leadership from PHE. PHE also gives relevant expert guidance and acquires national vaccine stock. NHSE currently commissions 17 national immunisation programmes in accordance with nationally agreed service specifications.²

VACCINATION SERVICES AND GENERAL PRACTICE

The majority of vaccination services are provided within general practice, although targeted neonatal *Bacillus Calmette-Guérin* (BCG), maternal vaccinations, and the first dose of targeted neonatal hepatitis B can also be provided by maternity units. School-age vaccinations and targeted neonatal BCG in the community are largely provided by community-based or school vaccination teams. Within London, community pharmacies have been commissioned to provide seasonal flu and adult pneumococcal (PPV23) vaccines to the London population.

There are situations, however, where vaccinations are indicated according to the Green Book³ — a government publication that provides the latest evidence-based guidance on immunisation — or other clinical guidance such as the National Institute for Health and Care Excellence (NICE). These are expected to be provided within clinical care but do not fall under S7a programme delivery.

Before 2013, all vaccinations were paid by primary care trusts (PCTs), but now it is unclear who pays for the vaccine and who pays for the administration. There are regional differences, with clinical commissioning groups in some areas

continuing the old PCT role whereas in others NHSE picks up the bill.

VACCINATIONS OUTSIDE OF S7A

Clearly local discussion is warranted between clinical commissioning groups (CCGs) and NHSE to agree a way forward for that area. In the meantime, solutions are needed for GPs who are dealing with patients requiring vaccination and, although we can only reflect on experience in London, we hope that it will stimulate further debate and resolution. Travel vaccines or those needed in an occupational context are not the focus of this article, as they are paid for privately or by the employer.

We identified four areas where vaccinations are indicated but are outside S7a's remit:

- as part of individual treatment, for example, tetanus vaccine in someone with incomplete immunity who had a road traffic accident;
- incomplete vaccination schedules requiring completion, for example, MMR in a teenager;
- vaccination of at-risk groups recommended by the Green Book but not covered by S7a, for example, pneumococcal vaccine (PCV13) for HIV patients as recommended by the British HIV Association,⁴ hepatitis B vaccine for a partner of a person infected with hepatitis B, or patients with certain clinical conditions such as diabetes, chronic renal failure, or chronic liver disease; and
- outbreaks of vaccine-preventable diseases where PHE recommends mass vaccinations following an outbreak of a vaccine-preventable disease; for example, MMR for prison staff and prisoners following a measles outbreak in a prison, or hepatitis A vaccine to a class following a case or cluster in a school.

The cost for these vaccines cannot be claimed under S7a and across England GP practices or CCGs are absorbing the costs, and in some cases charging patients. Arrangements for 'outbreak' mass vaccinations vary by region. In London, NHSE has 'Imms01', which is the commissioning protocol for the acquisition, distribution, and reimbursement of vaccinations in an outbreak of a vaccine-preventable disease. Under this, NHSE can mobilise 'immunisation task forces' as part of its contracted community

provision of school-age vaccinations. Sometimes GPs may be required to provide vaccination, for example, to <4-year-olds or the provision of hepatitis A vaccine during a community outbreak, and administration of such vaccines are reimbursed via the NHSE vaccination payments system, Calculating Quality Reporting Service (CQRS).

CLAIMING COSTS FOR VACCINATION

Claiming the cost of the vaccine can be more complicated. If immunisation task forces are mobilised, vaccines can be acquired via pharmacy hubs and the pharmacies reimbursed by Imms01. For GPs, this is a grey area, and costs of vaccines end up attributed to CCG prescription budgets, similarly to the seasonal flu vaccines.

It could be argued that, because S7a immunisation programme for seasonal flu covers clinical risk groups, other S7a programmes such as PCV13 should also include clinical risk groups, such as patients with chronic renal failure. This is dependent on the advice of the Joint Committee for Vaccinations and Immunisations (JCVI) who advise on the S7a immunisation programmes, which are then authorised by the DH for NHSE to commission. In the meantime, recommended vaccinations for clinical risk groups could be commissioned by the CCGs as part of care pathways.

In the past, vaccinations given in acute settings were covered under block contracts, but, as these are being phased out by the CCGs, the funding of such vaccinations in acute settings is also less clear. It is possible that at-risk groups covered by Specialised Commissioning in NHSE could have their vaccinations included in their contracts, and for the primary care setting a Local Enhanced Service (LES) agreement between NHSE and general practices could be pursued.

There are gaps in relation to where S7a responsibility ends. For example, for hepatitis B only neonates are covered by S7a despite the need to vaccinate a large range of people at risk from close contact with the infection or at high risk of infection (including siblings of the neonate or neonates with hepatitis B positive fathers). Similarly, S7a's BCG immunisation programme only covers infants <12 months of age in high-risk areas, but not vaccination of children aged 1–15 years living with close relatives from high prevalence areas. Nor does it cover close contacts of pulmonary TB cases who benefit from BCG.

Box 1. London payment process for 'off label' vaccines and vaccinations used outside Section 7a immunisation programmes

- Check guidance including relevant chapter of the Green Book and PHE recommendations on incomplete vaccinations (<https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>).
- Effectively this is a Prescription Specific Directive: vaccinations will need to be ordered directly from the manufacturer or can be obtained via the prescription portal (FP10). Vaccine stock on Immform is reserved for the national Section 7a programmes.
- For vaccine product reimbursement, claim via CCG using FP34D/PD for influenza, pneumococcal, meningococcal, hep A, hep B, typhoid; for all other vaccines, claim via FP10.
- For vaccine administration payments: as numbers are likely to be small and infrequent, payment falls under the GMS additional services (1.5% of global sum). Submit via CQRS to NHSE (London) or via Open Exeter (parameters amended by NHSE to reflect that incomplete vaccines fall within NHSE remit). Contact: england.londonimms@nhs.net.

Although it is difficult to quantify this, a rough estimate of risk groups suggests that the numbers are too substantial to just absorb. For example, there are an estimated 2 million people with diabetes aged 19–59 years and who are recommended for pneumococcal vaccine⁵ when applying age-specific prevalence rates,⁶ but currently not paid for by NHSE, not counting other recommended risk groups, such as those with chronic renal failure or chronic liver disease.

So how to claim? Under S7a programmes, some vaccines can be ordered directly from national stock via ImmForm for free, for example, MenACWY, rotavirus, and MenB. Other vaccines such as PPV23 and seasonal flu vaccine or neonatal hepatitis B can be obtained directly from the manufacturer and reimbursed via CCGs. Administration is reimbursed at £9.80 per vaccine by NHSE and is claimed via CQRS or Open Exeter (either a flat payment per vaccine or a target-based payment depending on the vaccine programme).

If the vaccine falls outside S7a and is clinically indicated, vaccines can be ordered and claimed for via prescription (FP34 or FP10). The administration of the vaccine can be claimed under 'additional services' from the global sum in the General Medical Services (GMS) contract.⁷ Guidance by the GPC/BMA is clear however that vaccines, particularly hep B, do not form part of the additional service component of the global sum:

'Giving hepatitis B for those at lifestyle or medical risk is not part of the additional service component of the global sum and commissioners should ensure that proper arrangements are in place for this service to be provided, either within practices or elsewhere. However, case-finding and call and recall would be more of a public health issue, and might be better served by a LES [Local Enhanced Service]. The GPC would

*encourage PCOs and Clinical Commissioning Groups to develop such LESs.*⁸

For 'off the label' vaccines, that is, vaccines given later or earlier than normally indicated in a S7a programme, such as an adolescent receiving MMR or new immigrants to the UK who should be vaccinated in accordance with the PHE's incomplete or unknown vaccination status algorithm.⁹

HELP FOR GENERAL PRACTICE AND THE FUTURE

In London, we have created an algorithm to help GP practices to claim for 'off the label' and clinically indicated vaccines (Box 1). We are currently in the process of implementation and hope it is a first step towards resolving the payment gap around vaccinations that fall outside national S7a immunisation programmes.

In summary, splitting public health responsibilities from PCTs previously to local authority, NHSE, and PHE resulted in budget discrepancies and resultant clinical risks, which need to be addressed urgently. There are a large number of patients who may be at risk of not getting adequately vaccinated due to confusing funding arrangements. The rationale by PHE in who is excluded and included from the S7a needs to be transparent and inform a discussion between GPs, CCGs, PHE, NHSE, and the DH as to how vaccinations will be funded going forward as a matter of urgency.

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