Section 7: Exclusions

Introduction

254. The national tariff is mandatory for activity within the scope of PbR. Some services, procedures, admitted patient care HRGs, outpatient TFCs, drugs and devices are outside the scope of PbR and therefore subject to locally agreed payments. The *2010-11 tariff information spreadsheet*, determined after wide-ranging consultation with stakeholders, gives a full list and further information. In addition, the costs of services that are currently outside the scope of reference costs are, by default, also outside the scope of PbR though will not necessarily be listed explicitly on the exclusions list.

255. There are various reasons why some activity should be subject to local payment rather than a mandatory tariff. Some excluded services have not had currencies developed for them. Excluded high cost drugs are typically specialist, and their use concentrated in a relatively small number of centres rather than evenly across all providers that carry out activity in the relevant HRGs. These drugs would therefore not be fairly reimbursed if they were funded through the tariff. Excluded medical devices represent a high and disproportionate cost relative to the cost covered under the relevant HRG. Since we largely base the national tariff on historic cost data submitted to us by the NHS, new medical devices introduced after the base year may not be fully reflected in the tariff price.

256. For all excluded activity, commissioners and providers should agree local prices, and local arrangements for monitoring activity. Non-mandatory prices are provided in Section 8 for a few services to help inform commissioning. Local prices should be paid in addition to the relevant admitted patient HRG, outpatient procedure HRG or outpatient attendance tariff. For example, if a patient is admitted to hospital for a procedure involving an endovascular stent graft, the normal HRG based tariff should be paid for the admitted patient spell, with an additional payment to cover the additional cost of the stent grant itself. This additional payment is the only part of the total price that will be subject to local determination.

257. In most cases, the additional payment should cover only the cost of the excluded drug, product or device and associated consumables and preparation. However, some procedures may entail additional direct costs over and above the cost of any drug, product, device and associated consumables and preparation, and these costs should also be taken into consideration in determining the appropriate additional payment. The level of this additional payment should be agreed between commissioners and providers, and local activity monitoring arrangements should be established.

Further information on payment for services outside the scope of the mandatory tariff can be found in the NHS standard contract[62].

258. In all cases, commissioners and providers will need to determine whether they wish to agree volumes and prices as part of contract agreements, or to operate on a case-by-case basis. For some excluded items, such as spinal cord stimulators or insulin pumps, it may be appropriate to agree volumes and prices in advance within a contract, while for others a case-by-case approach may be preferred. Commissioners and providers will also need to ensure that usage of any drugs or devices is in keeping with NICE and other clinical guidance.

259. There is some overlap between excluded high cost drugs and excluded services. The intention is that where services are excluded, the service as a whole is excluded. Certain service exclusions have flexibility for the method of exclusion to be determined locally (e.g. cystic fibrosis) whereas others are defined by set codes/variables. To avoid ambiguity, the list of excluded drugs therefore includes some drugs that may be used solely in services excluded from PbR.

260. Some services and procedures do not have their exclusion defined by specific codes, e.g. community services. We recommend that commissioners and providers discuss these exclusions using previous definitions as a starting point. These episodes can still be excluded from SUS PbR before processing by the use of the '=' exclusion.

261. Table 17 summarises the main changes to the exclusions list in 2010-11.

Table 17: Changes to the exclusions list

No longer excluded in 2010-11	Newly excluded in 2010-11
Services	
Patients in amenity beds (paragraph 264)	Spinal cord injury services undertaken in, or by, designated spinal cord injury centres
Procedures	
	Head and neck reconstructive surgery (paragraph 273)
Admitted patient care HRGs	
DZ30Z Chest Physiotherapy DZ37Z Non-Invasive Ventilation Support Assessment DZ38Z Oxygen Assessment and Monitoring DZ42Z TB Nurse Support EA08Z Pace 3 - Biventricular and all congenital pacemaker Procedures - Resynchronisation Therapy and other	CZ20Z Complex major maxillo-facial procedures with restoration DZ15A Asthma with major CC with intubation DZ21D Chronic obstructive pulmonary disease or bronchitis with intubation without CC HA84A Traumatic amputations with major CC HD35A Other wounds or injuries with major

[62] Available at http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Systemmanagement/DH_085048

No longer excluded in 2010-11	Newly excluded in 2010-11
(Catheterisation; EP; Ablation; Percutaneous Coronary Intervention) EA43Z Implantation of Prosthetic Heart or Ventricular Assist Device EB05Z Cardiac Arrest JC11Z Investigative procedures 3 JC19Z Electrical and other invasive therapy 4 JC29Z Phototherapy JC32Z Photochemotherapy SA14Z Plasma Exchanges 2 to 9 SA15Z Plasma Exchanges 10 to 19	CC HD35B Other Wounds or Injuries with CC HD35C Other Wounds or Injuries without CC JA04Z Pedicled Myocutaneous Breast Reconstruction with Insertion of Prosthesis LB43Z Treatment of Erectile Dysfunction LB45Z Retroperitoneal Lymph Node Dissection SA06D Myelodysplastic Syndrome with CC WA13Y Convalescent or other relief care without CC WA14Z Planned Procedures not carried out (paragraph 275)
Outpatient TFCs	
No changes	
Drugs	
Efalizumab	Alglucosidase alfa Antithymocyte Immunoglobulin Azacitadine C1 Esterase inhibitor Canakinumab Cladribine Co-careldopa internal tube intestinal gel Fomepizole Icatibant Plerixafor Privigen Rilonacept Romiplostim Temsirolimus Tesamorelin Tolvaptan Ustekinumab
Devices	
Balloon Kyphoplasty Biliary stents Cardiac Resynchronisation Therapy (CRT) Colorectal/colonic, oesophageal and pyloric stents CPAP/BiPAP (paragraph 290) Disposable hysteroscope Gastric Bands Gliadel wafers Implantable loop recorders Porcine collagen Ultrasonic dissecting devices	Artificial urinary sphincter Atherectomy devices Bone anchored hearing aids Bone growth stimulators Consumables associated with per oral/per anal single operator cholangioscope (includes Per-oral single operator cholangioscope and Biopsy Forceps for bile duct abnormalities (Spyglass)) Drug-eluting peripheral angioplasty balloon Maxillofacial bespoke prostheses (includes ear prostheses) Occluder vascular and septal devices (includes occluder septal devices) Radiofrequency ablation - probes and catheters (includes Surgical and percutaneous electrical ablation - probes and catheters) Ventricular Assist devices (VAD) (includes left VADs)

Excluded services

262. Major services not covered by a tariff include mental health, community, and ambulance services. Adult critical care (paragraph 293) and chemotherapy (paragraph 299) are considered later in this section. Other exclusions are largely unchanged from 2009-10.

263. We have made a minor amendment to the method for excluding neonatal critical care to bring it in line with paediatric and adult critical care (i.e. by excluding the neonatal critical care HRGs in sub-chapter XA).

264. In 2009-10 patients in amenity beds were excluded from PbR. This is a patient with an Administrative Category code of 03 in the CDS, and described in the NHS Data Model and Dictionary as "one who pays for the use of a single room or small ward in accord with section 12 of the NHS Act 1977, as amended by section 7(12) and (14) of the Health and Medicine Act 1988". Although the private element of paying for the use of a single room or small ward will remain outside the scope of PbR, and reference costs, we are no longer excluding the treatment or diagnosis of these patients from PbR in 2010-11. We would not expect payments made by patients to be netted off the tariff.

265. We are formalising spinal cord injury services undertaken in, or by, designated spinal cord injury centres as an exclusion in 2010-11. There are only a small number of spinal cord injury centres across the country and their services are commissioned separately by SCGs. Their activity tends to fall into basic HRGs such as minor pain or bladder procedures but is characterised with very long lengths of stay because the patients have spinal lesions and associated complications.

266. The tariffs do not include Patient Transport Services (PTS) and Healthcare Travel Costs Scheme (HTCS) costs. PCTs will need to commission PTS, and consider adjustments to non-tariff prices if necessary. Provider units (NHS trusts and NHS foundation trusts, or PCTs in cases where the provider is not an NHS trust) are legally obliged to pay the NHS travel expenses of eligible patients through the HTCS. PCTs will reimburse provider units for payments made under the scheme for all patients for whom they are the responsible commissioner.

Excluded procedures

267. We are continuing to exclude the following five procedures in 2010-11:

(a) soft tissue sarcoma surgery
(b) positron emission tomography computed tomography (PETCT)
(c) single photon emission computed tomography (SPECTCT)
(d) cardiovascular magnetic resonance imaging
(e) pelvic reconstructions.

Soft tissue sarcoma surgery

268. This surgery is only delivered in a very small number of units and is defined in Table 18 (conditions in both columns to be satisfied). Note that in 2010-11 the diagnosis of C47 (malignant neoplasm of peripheral nerves and autonomic nervous system) has been added to the definition.

Table 18: Definition of soft tissue sarcoma surgery procedure exclusion

ICD10 (in any position)	OPCS
C40 Malignant neoplasm of bone and articular cartilage of limbs C41 Malignant neoplasm of bone and articular cartilage of other and unspecified C47 Malignant neoplasm of peripheral nerves and autonomic nervous system C48 Malignant neoplasm of retroperitoneum and peritoneum C49 Malignant neoplasm of other connective and soft tissue	Primary operation code is not missing (i.e. a surgical procedure has actually been carried out), and it is not a chapter X code (chemotherapy or amputation)

PETCT

269. PETCT scans only had dedicated codes created for them in the OPCS coding classification in 2009-10 and the underlying reference costs do not reflect this type of scan. Therefore, we are continuing to exclude it in 2010-11.

SPECTCT

270. SPECTCT scans are excluded for the same reason as PETCT.

Cardiovascular Magnetic Resonance Imaging

271. There is some ongoing development work with the British Society of Cardiovascular Magnetic Resonance (BSCMR) on the coding and classification of this activity and until this work is completed, we are continuing to exclude it.

Pelvic reconstructions

272. Pelvic reconstructions are defined as “a pelvic/acetabular fracture requiring open reduction and internal fixation covering any significantly displaced acetabular fracture and all complex pelvic ring fractures (except those that are minimally displaced in the over 65s)”. We will continue to exclude them because they represent a disproportionate cost in relation to other activity within the same HRGs.

Head and neck reconstructive surgery

273. Head and neck reconstructive surgery (for the excision of and reconstruction for, upper aerodigestive tract, skull base, salivary and thyroid gland malignancies) ceased to be excluded with the introduction of HRG4 in 2009-10. However, we have been advised that this work is significantly more expensive than either excision or reconstruction alone and that a new HRG is required. We are therefore excluding this procedure whilst the HRG is being developed.

Excluded admitted patient care HRGs

274. In the main, admitted patient care HRG exclusions from 2009-10 are being carried forward to 2010-11.

Planned procedures not carried out

275. In 2010-11 we are also excluding planned procedures not carried out (WA14Z), after feedback that the tariff caused issues for the service in 2009-10. The reason why patients do not have a planned procedure carried out will include both legitimate clinical reasons and reasons that are related to organisational rather than clinical issues. Excluding this HRG from the scope of the mandatory tariff in 2010-11 will enable commissioners and providers to discuss the nature of any spells attracting WA14Z and agree what level of funding is appropriate. We are undertaking some work with the NHS Information Centre to review WA14Z.

Excluded outpatient TFCs

276. We are carrying forward outpatient TFCs that are excluded because of low volumes and, with the exception of dermatology (paragraph 333), not publishing non-mandatory prices.

Excluded drugs

277. The High Cost Drugs Steering Group has reviewed high cost drugs for 2010-11. They considered excluding high cost drugs where the:

    (a) drug, and its related costs, have a disproportionately high cost in relation to the other expected costs of care which would affect fair reimbursement and
    (b) drug has, or is expected to have more than £1.5 million expenditure or 600 cases in England each year.

278. Their review has included the UK Medicine information (UKMi) Horizon Scanning Report and has resulted in further exclusions.

279. The exclusions list contains details of the individual high cost drugs excluded from PbR as at 30 November 2009. Excluded drugs will also create unbundled HRGs where they are coded. In order to avoid obsolescence in our annual guidance, high cost drug exclusions are linked to British National Formulary (BNF)[63] categories where possible. As far as possible the generic names of medicines are used when referring to excluded drugs. Corresponding brand names can be found in the BNF. The general principle is that where a drug is a named exclusion it is excluded from both mandatory and published non-mandatory prices.

280. If a section or sub-section is listed then all drugs in that section or sub-section are excluded, e.g. under AIDS/HIV antiretrovirals it states “5.3.1”, in this instance all drugs under BNF section 5.3.1 are excluded.

281. If a specific drug is excluded then it is listed by name, e.g. under drugs affecting bone metabolism it states “6.6.1 > teriparatide”, in this instance only teriparatide is excluded.

282. The exclusions list is not necessarily an exhaustive list of all drugs excluded from PbR. The BNF is updated regularly but we will not be updating our list in-year. If in-year a new drug is added to a BNF section or sub-section that is wholly excluded then the new drug is also excluded. For example, if a new drug is added into BNF section 5.3.1 then it will be excluded from the tariff as the whole section is excluded, whereas if a new drug is added into

[63] Available at www.bnf.org.uk

BNF section 6.6.1 then it will not be excluded as currently only teriparatide is excluded in this section.

283. Most drugs are excluded for any purpose irrespective of their BNF section. However, BNF sections should be used as a broad guide to the usage and purpose of the drug. Commissioners and providers should agree locally for which indication(s) an excluded drug will be funded. Drugs can also be stated exclusions for a specific use or purpose. For example, in 2010-11 Sildenafil is only excluded (as part of BNF section 2.5.1/7.4.5) when used for pulmonary arterial hypertension.

284. Some drugs may be excluded from PbR prior to the drugs having the appropriate licensing or NICE guidance. This does not negate their exclusion from PbR. In addition, if a drug that is excluded from PbR is prepared as an unlicensed preparation it is still excluded from PbR. When a drug is excluded from PbR it is not an indication that the drug must necessarily be funded separately, but that the drugs costs have not been included in the published tariffs. We fully expect that commissioners and providers would discuss the usage and any associated payment for the drug through normal, established commissioning routes.

285. All home care drugs, where there is no associated admitted patient or outpatient activity at the provider, continue to be excluded from PbR. This includes the actual drug, transportation, delivery and any other associated costs

286. As in previous years, all blood products are excluded from PbR regardless of whether or not they are listed in the BNF.

Excluded devices

287. The High Cost Devices Steering Group has reviewed the list of high cost device exclusions for 2010-11. They considered existing exclusions and devices which were:

    (a) new to the NHS since 2007-08 and likely to be in use up to and including 2010-11
    (b) high cost and represented a disproportionate cost relative to the relevant HRG
    (c) used in a subset of cases within an HRG
    (d) used in a subset of providers delivering services under a specific HRG

288. As a result of the Group's review, we have subsumed some devices from the 2009-10 exclusion list within other exclusions in 2010-11, and revised some device headings to make the exclusion more specific. We have removed devices from the list where the Group advised that they do not

meet the exclusion criteria. The reasons for this included low volumes, low cost, or costs being adequately reflected in the tariff. The Group also considered how and when future HRG design will reflect the relevant procedure and where appropriate made a commitment to exclude in 2010-11 and 2011-12.

289. Table 19 summarises changes to the 2009-10 device exclusion list. It does not include the new additions to the list in 2010-11 from Table 17.

Table 19: Changes to the 2009-10 device exclusion list

Name of device in 2009-10	Comments
3 dimensional navigation system mapping catheters	2010-11 exclusion and would expect to be excluded in 2011-12
Aneurysm coils	2010-11 exclusion
Aortic stent grafts	Now covered under the heading of Endovascular stent grafts
Balloon Kyphoplasty	Not 2010-11 exclusion – did not meet exclusion criteria (paragraph 292)
Bespoke orthopaedic prostheses*	2010-11 exclusion
Biliary stents	Not 2010-11 exclusion - Now covered by relevant HRGs
Devices used in connection with pulmonary artery banding	2010-11 exclusion
Cardiac Resynchronisation Therapy (CRT)	Not 2010-11 exclusion - Now covered by relevant HRGs
Carotid, iliac and renal stents	2010-11 exclusion
Colorectal-colonic, oesophageal and pyloric stents	Not 2010-11 exclusion - Now covered by relevant HRGs
Consumables for robotic surgery	2010-11 exclusion and would expect to be excluded in 2011-12
CPAP-BiPAP	Not 2010-11 exclusion - To be covered under loan equipment (paragraph 290)
Deep brain, vagal, sacral, spinal cord and occipital nerve stimulators	2010-11 exclusion
Disposable hysteroscope	Not 2010-11 exclusion - Did not meet exclusion criteria, as is not considered high cost
Ear prostheses	Now covered under the heading of Maxillofacial bespoke prostheses
Endovascular stent graft	2010-11 exclusion
Gastric Bands	Not 2010-11 exclusion - Now covered by relevant HRG
Gliadel wafers	Not 2010-11 exclusion – now covered under chemotherapy exclusion
ICD with CRT capability	2010-11 exclusion
Illizarov frames	2010-11 exclusion
Implantable defibrillators (ICD)	2010-11 exclusion
Implantable loop recorders	Not 2010-11 exclusion - can now be mapped to a single chamber pacemaker implant.
Insulin pumps and pump consumables	2010-11 exclusion
Intracranial stents	2010-11 exclusion
Intrathecal drug delivery pumps	2010-11 exclusion
Left Ventricular Assist devices (VAD)	Now covered under the heading of Ventricular Assist devices (VAD)

Name of device in 2009-10	Comments
Minimal Invasive Mitral Valve Replacement Pack	Now covered under the heading of Percutaneous valve replacement devices
Occluder septal devices	Name changed to Occluder vascular and septal devices
Penile prosthesis	2010-11 exclusion
Percutaneous valve replacement devices	2010-11 exclusion
Peripheral vascular stents	2010-11 exclusion
Per-oral single operator cholangioscope and Biopsy Forceps for bile duct abnormalities (Spyglass)	Name changed to Consumables associated with per oral-per anal single operator cholangioscope
Porcine Collagen	Not 2010-11 exclusion - Now covered by relevant HRG or part of an excluded HRG (breast reconstruction surgery)
Surgical and percutaneous electrical ablation - probes and catheters	Device name made more specific to reflect the original intention -Radiofrequency ablation - probes and catheters – would also expect to be excluded for 2011-12
Ultrasonic dissecting devices (harmonic scalpel)	Not 2010-11 exclusion - Did not meet the high cost exclusion criteria
Video Capsule for Endoscopy	2010-11 exclusion but expect to be covered by specific HRG in tariff for 2011-12

290. As set out in paragraphs 12 and 254, the costs of services that are currently outside the scope of reference costs are, by default, not included within the mandatory or non-mandatory tariffs. We expect that commissioners and providers will negotiate locally for these services and devices in the same way as for other services and devices excluded from mandatory tariff. For example, Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airways Pressure (BiPAP) machines (which we have removed from the exclusions list) should now be covered under local commissioning arrangements for equipment in hospital and home equipment loans.

291. As in 2009-10, commissioners and providers should agree an additional payment to cover the additional cost of a bespoke prosthesis, over and above the cost of a standard prosthesis. Commissioners and providers should also agree a local price for the programming and maintenance of cochlear implants and bone anchored hearing aids because the tariffs only cover the costs associated with the admitted patient spell in which the device is implanted. For bilateral procedures, the additional cost of the procedure and implant should be subject to local negotiation.

292. Where devices have been removed from the exclusions list, commissioners and providers may wish to consider the use of innovation payments, previously known as pass through payments (paragraph 408), to support funding.