

## PART 12

DRUGS TO BE PRESCRIBED IN CERTAIN CIRCUMSTANCES UNDER THE NHS  
PHARMACEUTICAL SERVICES

## SCHEDULE 2

DRUGS, MEDICINES AND OTHER SUBSTANCES TO BE ORDERED BY CONTRACTORS  
IN THE PROVISION OF PRIMARY MEDICAL SERVICES UNDER A GENERAL MEDICAL  
SERVICES CONTRACT ONLY IN CERTAIN CIRCUMSTANCES

1 Drug, medicine or other substance	2 Patient	3 Purpose
Clobazam	Any patient	Treatment of epilepsy
Cyanocobalamin Tablets	Any patient who is a vegan or who has a proven vitamin B12 deficiency of dietary origin	Treatment or prevention of vitamin B12 deficiency
Locabital Aerosol	Any patient	Treatment of infections and inflammation of the oropharynx
Niferex Elixir 30 ml Paediatric Dropper Bottle	Infants Born Prematurely	Prophylaxis and Treatment of Iron Deficiency
Nizoral Cream	Any patient	Treatment of Seborrhoeic Dermatitis and Pityriasis Versicolor
Alprostadil (Caverject), (MUSE), (Viridal)	(a) A man with erectile dysfunction who on 14 <sup>th</sup> September 1998 was receiving treatment under the Act, the National Health Service Act 1977 or the Health and Personal Social Services (Northern Ireland) Order 1972(d) for this condition with any of the following drugs –	Treatment of erectile dysfunction
Apomorphine Hydrochloride (sublingual tablets) (Uprima)		
Moxisylyte Hydrochloride (Erecnos)		
Tadalafil (Cialis)		
Thymoxamine Hydrochloride (Erecnos)		Alprostadil (Caverject), (MUSE), (Viridal)
Vardenafil (Levitra)		Apomorphine Hydrochloride (sublingual tablets) (Uprima)
Sildenafil (Viagra)	Moxisylyte Hydrochloride (Erecnos)	
	Tadalafil (Cialis)	
	Thymoxamine Hydrochloride (Erecnos)	
	Vardenafil (Levitra)	
	Sildenafil (Viagra); or	
	(b) a man who is a national of an EEA State who is entitled to treatment by virtue of Article 7(2) of Council Regulation 1612/68(a) as extended by the EEA Agreement or by virtue of any other enforceable	

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Community right who has  
erectile dysfunction and was  
on 14<sup>th</sup> September 1998  
receiving a course of treatment  
under a national health  
insurance scheme of an EEA  
State for this condition with any  
of the drugs listed in sub-  
paragraph (a); or

(c) a man who is not a national  
of an EEA state but who is the  
member of the family of such a  
national who has an  
enforceable Community right to  
be treated no less favourably  
than the national in the  
provision of medical treatment  
and has erectile dysfunction  
and was being treated for that  
condition on 14<sup>th</sup> September  
1998 with any of the drugs  
listed in sub-paragraph (a); or

(d) a man who is suffering from  
any of the following –

diabetes  
multiple sclerosis  
Parkinson's disease  
Poliomyelitis  
prostate cancer  
severe pelvic injury  
single gene neurological  
disease  
spina bifida  
spinal cord injury; or

(e) a man who is receiving  
treatment for renal failure by  
dialysis; or

(f) a man who has had the  
following surgery –

prostatectomy  
radical pelvic surgery  
renal failure treated by  
transplant.

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1 Drug, medicine or other substance	2 Patient	3 Purpose
Oseltamivir (Tamiflu)	<p>(a) clinical priority group patients and at-risk patients where—</p> <p>(1) It has been determined in accordance with a community based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating;</p> <p>(2) the patient has an influenza-like illness; and</p> <p>(3) the patient can start therapy within 48 hours of the onset of symptoms.</p> <p>(b) Any patient suffering from influenza during an outbreak of influenza.</p>	Treatment of influenza
Oseltamivir (Tamiflu)	<p>(a) clinical priority group patients and at-risk patients where—</p> <p>(1) It has been determined in accordance with a community based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides;</p> <p>(2) the patient has been exposed to an influenza-like illness through being in close contact with someone with whom the patient lives who is or has been suffering from an influenza-like illness;</p> <p>(3) the patient is not effectively protected by vaccination against influenza because the patient—</p> <p>(i) has not been vaccinated because vaccination is contraindicated;</p> <p>(ii) has not been vaccinated since the previous influenza season;</p> <p>(iii) has been vaccinated but it has yet to take effect;</p> <p>or</p>	Prophylaxis of influenza

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	<ul style="list-style-type: none"> <li>(iv) has been vaccinated but the vaccine is not well matched to the strain of influenza circulating in the locality in which the patient resides or is or has been present;</li> <li>(4) the patient lives in a residential care establishment and another resident or member of staff of the establishment has an influenza-like illness; and</li> <li>(5) the patient can start prophylaxis within 48 hours of exposure to an influenza-like illness.</li> </ul>	
	<ul style="list-style-type: none"> <li>(b) Any patient at risk from influenza during an outbreak of influenza.</li> </ul>	
Zanamivir (Relenza)	<ul style="list-style-type: none"> <li>(a) clinical priority group patients and at-risk patients where—           <ul style="list-style-type: none"> <li>(1) It has been determined in accordance with a community based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides or is present or was present at the time that the virus was circulating;</li> <li>(2) the patient has an influenza-like illness; and</li> <li>(3) the patient can start therapy within 48 hours of the onset of symptoms.</li> </ul> </li> </ul>	Treatment of influenza
	<ul style="list-style-type: none"> <li>(b) Any patient at risk of or suffering from influenza during an outbreak of influenza .</li> </ul>	Prophylaxis or treatment of influenza
Zanamivir (Relenza)	<ul style="list-style-type: none"> <li>(a) clinical priority group patients and at-risk patients where—           <ul style="list-style-type: none"> <li>(1) It has been determined in accordance with a community based virological surveillance scheme that influenza A or influenza B is circulating in the locality in which the patient resides;</li> <li>(2) the patient has been exposed to an influenza-like illness through being in close</li> </ul> </li> </ul>	Prophylaxis of influenza

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- contact with someone with whom the patient lives who is or has been suffering from an influenza-like illness;
- (3) the patient is not effectively protected by vaccination against influenza because the patient—
- (i) has not been vaccinated because vaccination is contraindicated;
  - (ii) has not been vaccinated since the previous influenza season;
  - (iii) has been vaccinated but it has yet to take effect;
- or
- (iv) has been vaccinated but the vaccine is not well matched to the strain of influenza circulating in the locality in which the patient resides or is or has been present;
- (4) the patient lives in a residential care establishment and another resident or member of staff of the establishment has an influenza-like illness; and
- (5) the patient can start prophylaxis within 48 hours of exposure to an influenza-like illness.

In this Schedule –

‘clinical priority group’ means

- People aged over six months who are at risk-patients.
- All pregnant women;
- Those who have been or who are in close contact with people with compromised immune systems e.g. people in regular close contact with patients on treatment for cancer
- Frontline health and social care workers.

“at-risk” means a patient who falls into the ‘clinical risk category’ listed in the table below.

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Clinical Risk Category	Examples (but decisions should be based on clinical judgement)
Chronic respiratory disease, including asthma	<ul style="list-style-type: none"> <li>• Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD)</li> <li>• Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission</li> <li>• Children who have previously been admitted to hospital for lower respiratory tract disease</li> </ul>
Chronic heart disease	<ul style="list-style-type: none"> <li>• Congenital heart disease</li> <li>• Hypertension with cardiac complications</li> <li>• Chronic heart failure</li> <li>• Individuals requiring regular medication and/or follow-up for ischaemic heart disease</li> </ul>
Chronic renal disease	<ul style="list-style-type: none"> <li>• Chronic renal failure</li> <li>• Nephrotic syndrome</li> <li>• Renal transplantation.</li> </ul>
Chronic liver disease	<ul style="list-style-type: none"> <li>• Cirrhosis</li> <li>• Biliary Atresia</li> <li>• Chronic hepatitis</li> </ul>
Chronic neurological disease	<ul style="list-style-type: none"> <li>• Cerebrovascular disease, principally stroke and transient ischaemic attacks (TIAs)</li> <li>• Multiple sclerosis and related conditions</li> <li>• Hereditary and degenerative disease of the central nervous system</li> </ul>
Diabetes Mellitus	<ul style="list-style-type: none"> <li>• Type 1 diabetes</li> <li>• Type 2 diabetes (including treatment by insulin, oral hypoglycaemic drugs or diet alone)</li> </ul>
Immunosuppression	<ul style="list-style-type: none"> <li>• Immunosuppression due to disease or treatment</li> <li>• Patients undergoing chemotherapy leading to immunosuppression</li> <li>• Asplenia or splenic dysfunction</li> <li>• HIV infection</li> <li>• Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mgs or more per day (any age) or for children under 20 kgs a dose of 1mg or more per kg per day.</li> <li>• Some immunocompromised patients may have a suboptimal immunological response to the vaccine</li> </ul>

“child” means any person under the age of 16;

“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2<sup>nd</sup> May 1992 (a) as adjusted by the Protocol signed at Brussels on 17<sup>th</sup> March 1993 (b);

“EEA State” means a state which is a contracting party to the EEA Agreement or Switzerland;

“residential care establishment” means a place where persons reside on a long term basis in order to receive continuing care.

(a) Cm 2073 and O.J. No. L1, 3.1.1994 p.3

(b) Cm 2183 and O.J. No. L1, 3.1.1994 p.3

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**CRITERIA NOTIFIED UNDER THE TRANSPARENCY DIRECTIVE**

**Criteria notified to the European Commission under Article 7 of the Council Directive relating to the transparency of measures relating to the pricing of medicinal products for human use and their inclusion in the scope of the national health insurance schemes (89/105/EEC)**

The following six criteria have been separately notified by the UK Government to the European Commission since 1989 to comply with Article 7 of the Transparency Directive.

First, under the Selected List Scheme, medicinal products in seventeen therapeutic categories which are excluded from prescription on the grounds that, on expert advice, they had no clinical or therapeutic advantage over other, cheaper drugs in the following categories: -

- Mild to moderate painkillers
- Indigestion remedies
- Laxatives
- Cold and cough remedies
- Vitamins
- Tonics
- Benzodiazepine sedatives and tranquillisers
- Anti-diarrhoeal drugs
- Drugs for allergic disorders
- Hypnotics and anxiolytics
- Appetite Suppressants
- Drugs for vaginal and vulva conditions
- Contraceptives
- Drugs used in anaemias
- Topical anti-rheumatics
- Drugs acting on the ear and nose
- Drugs acting on the skin

Second, products may be considered as 'borderline substances', which are not truly medicinal products with clinical or therapeutic value, and are excluded from NHS prescription on that ground.

Third, as well as being freely on sale over the counter to the general public the cost to the NHS if the product (s) were to be supplied on prescription could not be justified at any price likely to be economic to the manufacturer and that supply of the product is not considered a priority for the use of the limited resources available to the NHS.

Fourth, the products which nevertheless may meet a legitimate clinical or therapeutic need when properly prescribed, are subject to misuse by drug misusers, and such misuse, or the manner in which the product may be administered by drug misusers, gives rise to the risk of physical or mental morbidity and alternative products may be available to meet all legitimate clinical or therapeutic needs.

Fifth, a medicinal product or category of medicinal products may be excluded entirely from supply on NHS prescription. It may alternatively be excluded except in specified circumstances, or except in relation to specified conditions or categories of conditions, or specified categories of patients. A medicinal product or category of them may be so excluded where the forecast aggregate cost to the NHS of allowing the product (or category of products) to be supplied on NHS prescription, or to be supplied more widely than the permitted exceptions, could not be justified having regard to the relevant circumstances including in particular: the First Minister's duties pursuant to the NHS (Scotland) Act 1978 and the priorities for the expenditure of NHS resources.

Sixth, products, which comprise an injection device prefilled with a drug may be excluded from supply on NHS prescription if the same drug is available and can be used more economically in a container which may be used in conjunction with a refillable injection device.

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