OFFERYNNAU STATUDOL CYMRU

WELSH STATUTORY INSTRUMENTS

2024 Rhif 774 (Cy. 115)

2024 No. 774 (W. 115)

Y GWASANAETH IECHYD GWLADOL, CYMRU

NATIONAL HEALTH SERVICE, WALES

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2024

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2024

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

Mae'r Rheoliadau hyn yn diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) 2004 (O.S. 2004/1022 (Cy. 119)) ("y prif Reoliadau"), sy'n gwneud darpariaeth ynghylch y cyffuriau, y meddyginiaethau neu'r sylweddau eraill y caniateir eu harchebu ar gyfer cleifion wrth ddarparu gwasanaethau meddygol o dan gontract gwasanaethau meddygol cyffredinol ("contract GMC") o fewn ystyr adran 42 o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006 (p. 42).

Mae rheoliad 2 yn gwneud diwygiadau i'r tabl yn Atodlen 2 i'r prif Reoliadau (cyffuriau neu feddyginiaethau sydd i'w harchebu o dan amgylchiadau penodol yn unig), sy'n cyfyngu ar yr amgylchiadau pryd y caniateir archebu cyffuriau a meddyginiaethau a bennir yng ngholofn 1 o'r tabl ar gyfer y categori o gleifion a ddisgrifir yng ngholofn 2 o'r tabl at y diben a bennir yng ngholofn 3 o'r tabl.

Mae rheoliad 2(2)(a) i (c) yn cyfyngu ar yr amgylchiadau pryd y caniateir archebu cyffuriau a meddyginiaethau sydd wedi eu cyfansoddi o analogau hormonau sy'n rhyddhau gonadotroffin ("GnRH"), neu sy'n cynnwys analogau GnRH.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 (S.I. 2004/1022 (W. 119)) ("the principal Regulations"), which make provision as to the drugs, medicines or other substances that may be ordered for patients in the provision of medical services under a general medical services contract ("GMS contract") within the meaning of section 42 of the National Health Service (Wales) Act 2006 (c. 42).

Regulation 2 makes amendments to the table in Schedule 2 to the principal Regulations (drugs or medicines to be ordered only in certain circumstances) which restricts the circumstances in which drugs and medicines specified in column 1 of the table may be ordered for the category of patients described in column 2 of the table for the purpose specified in column 3 of the table.

Regulation 2(2)(a) to (c) restricts the circumstances in which drugs and medicines that consist of or contain gonadotrophin-releasing hormone analogues may be ordered.

Mae rheoliad 2(2)(d) yn dileu'r cyfyngiad ar archebu Tabledi Cyanocobalamin ar gyfer trin neu atal diffyg fitamin B12.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, lluniwyd asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn. Gellir cael copi oddi wrth: Y Grŵp Iechyd a Gwasanaethau Cymdeithasol, Llywodraeth Cymru, Parc Cathays, Caerdydd CF10 3NQ.

Regulation 2(2)(d) removes the restriction on ordering Cyanocobalamin Tablets for the treatment or prevention of vitamin B12 deficiency.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained by contacting the Health and Social Services Group, Welsh Government, Cathays Park, Cardiff CF10 3NQ.

2024 Rhif 774 (Cy. 115)

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2024

Gwnaed	*27 Mehefin 2024*
Gosodwyd gerbron Senedd Cymru	*28 Mehefin 2024*
Yn dod i rym	*19 Gorffennaf 2024*

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddir gan adrannau 46(2), 203(9) a (10) a 204(1)(b) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(**1**), yn gwneud y Rheoliadau a ganlyn.

Enwi a dod i rym

1. Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) (Diwygio) 2024 a deuant i rym ar 19 Gorffennaf 2024.

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) 2004

2.—(1) Mae Atodlen 2 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau Etc.) (Cymru) 2004(**2**) wedi ei diwygio fel a ganlyn.

(**1**) 2006 p. 42.
(**2**) O.S. 2004/1022 (Cy. 119), a ddiwygiwyd gan O.S. 2005/366 (Cy. 32), O.S. 2009/1838 (Cy. 166), O.S. 2009/1977 (Cy. 176), O.S. 2011/1043, O.S. 2012/1916, O.S. 2013/683 (Cy. 81), O.S. 2014/109 (Cy. 09), O.S. 2016/90 (Cy. 43), ac O.S. 2020/1396 (Cy. 309).

2024 No. 774 (W. 115)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2024

Made	*27 June 2024*
Laid before Senedd Cymru	*28 June 2024*
Coming into force	*19 July 2024*

The Welsh Ministers in exercise of the powers conferred by sections 46(2), 203(9) and (10) and 204(1)(b) of the National Health Service (Wales) Act 2006(**1**), make the following Regulations.

Title and coming into force

1. The title of these Regulations is the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2024 and they come into force on 19 July 2024.

Amendment to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004

2.—(1) Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004(**2**) is amended as follows.

(**1**) 2006 c. 42.
(**2**) S.I. 2004/1022 (W. 119), amended by S.I. 2005/366 (W. 32), S.I. 2009/1838 (W. 166), S.I. 2009/1977 (W. 176), S.I. 2011/1043, S.I. 2012/1916, S.I. 2013/683 (W. 81), S.I. 2014/109 (W. 09), S.I. 2016/90 (W. 43), and S.I. 2020/1396 (W. 309).

(2) Yn y tabl—

(a) yng ngholofn 1 o'r tabl (*cyffuriau*), yn y lle priodol mewnosoder "GnRH analogue";

(b) yng ngholofn 2 (*claf*), yn y lle priodol mewnosoder—

"(1) Any patient who is aged 18 or over.

(2) Any patient who is aged under 18 to whom the general medical practitioner is providing treatment under the contract which does not include treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.

(3) Any patient who is aged under 18, and who—

(a) before 19 July 2024, started a course of treatment with a GnRH analogue for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both, and in this context, a person is treated as having started a course of treatment with a GnRH analogue if, on or after 3 December 2023, that person was issued with a NHS or private prescription for a GnRH analogue, whether or not the prescription has been dispensed or the prescribed GnRH analogue has been taken by that person before 19 July 2024; or

(b) is being treated with a GnRH analogue as part of a National Institute for Health and Care Research clinical trial related to treatment with a GnRH analogue for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.";

(c) yng ngholofn 3 (*cyflwr*), yn y lle priodol mewnosoder—

"(1) Treatment for any purpose.

(2) Treatment for any purpose other than treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.

(3) Treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.";

(d) yng ngholofn 1 (*cyffuriau*), hepgorer y cofnod ar gyfer "Cyanocobalamin Tablets" a'r rhan gyfagos sy'n ymwneud â'r disgrifiad o'r claf (colofn 2) a'r cyflwr (colofn 3).

(2) In the table—

(a) in column 1 of the table (*drugs*), at the appropriate place insert "GnRH analogue";

(b) in column 2 (*patient*), at the appropriate place insert—

"(1) Any patient who is aged 18 or over.

(2) Any patient who is aged under 18 to whom the general medical practitioner is providing treatment under the contract which does not include treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.

(3) Any patient who is aged under 18, and who—

(a) before 19 July 2024, started a course of treatment with a GnRH analogue for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both, and in this context, a person is treated as having started a course of treatment with a GnRH analogue if, on or after 3 December 2023, that person was issued with a NHS or private prescription for a GnRH analogue, whether or not the prescription has been dispensed or the prescribed GnRH analogue has been taken by that person before 19 July 2024; or

(b) is being treated with a GnRH analogue as part of a National Institute for Health and Care Research clinical trial related to treatment with a GnRH analogue for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.";

(c) in column 3 (*condition*), at the appropriate place insert—

"(1) Treatment for any purpose.

(2) Treatment for any purpose other than treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.

(3) Treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.";

(d) in column 1 (*drugs*), omit the entry for "Cyanocobalamin Tablets" and the adjacent part which relates to the description of the patient (column 2) and the condition (column 3).

(3) Ar ddiwedd y tabl, yn y ddarpariaeth ddehongli, yn y lle priodol mewnosoder—

> ""general medical practitioner" means a medical practitioner whose name is included in the General Practitioner Register, kept by the General Medical Council under section 2 of the Medical Act 1983(**1**);
>
> "GnRH analogue" means gonadotrophin-releasing hormone, a medicinal product that consists of or contains buserelin, gonadorelin, goserelin, leuprorelin acetate, nafarelin or triptorelin;".

(4) Ar ddiwedd y tabl, yn y ddarpariaeth ddehongli, yn y diffiniad o "patient", yn lle "National Health Services (General Medical Services Contracts) (Wales) Regulations 2004" rhodder "National Health Services (General Medical Services Contracts) (Wales) Regulations 2023(**2**)".

(3) At the end of the table, in the interpretation provision, at the appropriate place insert—

> ""general medical practitioner" means a medical practitioner whose name is included in the General Practitioner Register, kept by the General Medical Council under section 2 of the Medical Act 1983(**1**);
>
> "GnRH analogue" means gonadotrophin-releasing hormone, a medicinal product that consists of or contains buserelin, gonadorelin, goserelin, leuprorelin acetate, nafarelin or triptorelin;".

(4) At the end of the table, in the interpretation provision, in the definition of "patient", for "National Health Service (General Medical Services Contracts) (Wales) Regulations 2004" substitute "National Health Services (General Medical Service Contracts) (Wales) Regulations 2023(**2**)".

Eluned Morgan

Ysgrifennydd y Cabinet dros Iechyd a Gofal Cymdeithasol, un o Weinidogion Cymru
27 Mehefin 2024

Cabinet Secretary for Health and Social Care, one of the Welsh Ministers
27 June 2024

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Argraffwyd a chyhoeddwyd yn y DU gan Y Llyfrfa Cyf dan awdurdod a goruchwyliaeth Jeff James, Rheolwr Llyfrfa Ei Fawrhydi ac Argraffydd Deddfau Senedd y Brenin.

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(**1**) 1983 p. 54. Diwygiwyd adran 2 gan O.S. 2002/3135, O.S. 2006/1914, O.S. 2007/3101, O.S. 2008/1774, O.S. 2014/1101 ac O.S. 2019/593.
(**2**) O.S. 2023/953 (Cy. 155).

(**1**) 1983 c. 54. Section 2 was amended by S.I. 2002/3135, S.I. 2006/1914, S.I. 2007/3101, S.I. 2008/1774, S.I. 2014/1101 and S.I. 2019/593.
(**2**) S.I. 2023/953 (W. 155).

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