

WELSH HEALTH CIRCULAR



Llywodraeth Cymru
Welsh Government

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STATUS: COMPLIANCE and ACTION

CATEGORY: LEGISLATION and POLICY

Title: The New Treatment Fund - Access to medicines recommended by the National Institute for Health and Care Excellence (NICE) and the All-Wales Medicines Strategy Group (AWMSG).

Date of Expiry / Review 31 March 2019

For Action by:
Local Health Boards and NHS Trusts in Wales

Action required by: 26.4.17

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Title: New Treatment Fund - Directions to all Local Health Boards and NHS Trusts in Wales on the new implementation timescales for Health Technology Appraisals by the National Institute for Health and Care Excellence (NICE) and the All-Wales Medicines Strategy Group (AWMSG).

Dear Colleague

Purpose

1. To advise you of the new Directions which comes into force from 26 April 2017. This new Direction amends Directions to Local Health Boards and NHS Trusts in Wales 2003 and the Managed Introduction of New Medicines into the National Health Service in Wales Directions 2009.

Background

2. The Welsh Government's New Treatment Fund was announced in January 2017. The fund will support health boards to introduce new, recommended medicines faster and more consistently across Wales. This is a key commitment within the programme for Government – Taking Wales Forward.
3. The fund will make £80 million available over the life of this Assembly commencing 2016-17, providing health boards with additional, annual funding of £16 million until 31 March 2021. The fund will be allocated under the agreed allocation formula used to distribute discretionary allocations.
4. The fund is ring-fenced to ensure it is used for the intended purpose of supporting health boards to make all new medicines recommended by NICE and AWMSG available faster and more consistently across Wales. The fund will help ease the financial pressures that can be associated with the introduction of new medicines, providing health boards with the time to plan to invest in future years.

New Requirements for Health Boards and Trusts

5. The Directions require all health boards to make medicines recommended by NICE and AWMSG available as soon as is reasonably practicable and certainly within two months of the published recommendation. NHS Trusts in Wales are required to co-operate with

Local Health Boards to facilitate compliance with the Directions. This applies as follows:

i) AWMSG Health Technology Appraisals (including the orphan and ultra-orphan appraisal process)

All new medicines recommended by AWMSG within two months of the published decision.

ii) Nice Health Technology Appraisals and Highly Specialised Technology Appraisals

All new medicines recommended by NICE (including those appraised under the Highly Specialised Technologies programme) within two months of the first publication of the Final Appraisal Determination (FAD), rather than the publication of the final Technology Appraisal Guidance which is published following the appeal period.

iii) Cancer Drugs – NHS England Cancer Drug Fund

Cancer medicines recommended for an interim period by NICE for funding through the NHS England Cancer Drug Fund, within two months of the first publication by NICE of the Final Appraisal Determination.

iv) Extension to the Timescale

A three month timescale for the introduction of a medicine is being retained for use in exceptional circumstances, where the scale of service planning required will need longer than two months.

Where a Local Health Board or NHS Trust determines a longer implementation timeframe is required, a notification must be made in writing to the Welsh Government's Chief Medical Officer. The notification must be made within 3 weeks of the publication of the AWMSG recommendation or the NICE FAD and must provide the reasons for that decision.

Compliance and Monitoring

6. The Cabinet Secretary for Health, Well-being and Sport wrote to health board and trust chairs on 17 January 2017 announcing the establishment of the New Treatment Fund. This letter also accompanied a release of the first tranche of funding and advised that health boards and trusts were expected to implement the new timeframes quickly and utilise the additional £16 million being provided in 2016-17 to assist in the implementation of the new timeframes. A similar letter issued from Simon Dean, the Deputy Chief Executive of NHS Wales on 13 January 2017.

7. Health board and trust chief executives and chairs were asked to ensure they had assurances that their systems and processes for introducing new medicines are efficient and support compliance with the new timescales.

8. The NHS Wales Delivery Framework for 2017-18 contains the following indicator:

All new medicines recommended by AWMSG and NICE, including interim recommendations for cancer medicines, must be made available where clinically appropriate, no later than two months from the publication of the NICE Final Appraisal Determination and the AWMSG appraisal recommendation.

9. The current monitoring system for measuring health board compliance with medicine appraisal timescales is being strengthened. Key contacts are Kath Haines at the All-Wales Therapeutics and Toxicology Centre and Robin Burfield at the NHS Wales Informatics Service (NWIS). Data on usage to support measuring compliance is being drawn from health board and trust formulary data and the NWIS Medusa system which collates data from hospital pharmacy systems.

Reporting

10. Reports will be monthly by health board aggregated to the All-Wales level and will be available to health boards and trusts for management information purposes.

11. The first report of compliance will be for the final quarter ending 31 March 2017. Chief executives will be asked to consider progress at the executive board meeting scheduled for 25 April 2017.

12. Health and trust boards will be expected to monitor compliance and report regularly within the context of the NHS Delivery Framework.

13. The Cabinet Secretary will be seeking progress reports routinely from health board and trust chairs. He will also be reporting progress to the National Assembly for Wales on 4 July 2017 by Oral Statement. It is anticipated bi-annual progress reports will continue throughout the five year period of the New Treatment Fund.

Release of Funding

14. Funding for 2017-18 will be released retrospectively for quarter one. Prospective release will be considered predicated on evidence of compliance with the new timeframes.

2017 No. 17

**NATIONAL HEALTH
SERVICE (WALES) ACT 2006**

**DIRECTIONS TO LOCAL
HEALTH BOARDS AND NHS
TRUSTS IN WALES 2003 AND
THE MANAGED
INTRODUCTION OF NEW
MEDICINES INTO THE
NATIONAL HEALTH
SERVICE IN WALES
DIRECTIONS 2009
(AMENDMENT) (WALES)
DIRECTIONS 2017**

Made 19 April 2017

Coming into force 26 April 2017

The Welsh Ministers, in exercise of the powers conferred on them by sections 12(3), 19(1), 174(10), 203(9) and (10) and 204(1) of the National Health Service (Wales) Act 2006(1) give the following Directions.

Title, commencement, application and interpretation

1.—(1) The title of these Directions is the Directions to Local Health Boards and NHS Trusts in Wales 2003 and the Managed Introduction of New Medicines into the National Health Service in Wales Directions 2009 (Amendment) (Wales) Directions 2017.

(2) These Directions come into force on 26 April 2017 and apply to every Local Health Board and NHS Trust in Wales.

(3) In these Directions—

(i) 2006 c. 42.

"the 2003 Directions" ("*Cyfarwyddydau 2003*") means the Directions to Local Health Boards and NHS Trusts in Wales, dated 23 October 2003, as amended(1);

"the 2009 Directions" ("*Cyfarwyddydau 2009*") means the Managed Introduction of New Medicines into the National Health Service in Wales Directions 2009(2);

"AWMSG" ("*GSFCG*") means the All Wales Medicines Strategy Group;

"endorsed by the Minister" ("*wedi ei ardstio gan y Gweinidog*") means the acceptance by the Welsh Ministers of a recommendation made by the AWMSG;

"Technology Appraisal Guidance" ("*Canllawiau Gwerthuso Technoleg*") means Technology Appraisal Guidance issued by the National Institute for Health and Care Excellence(3) in accordance with their published procedures.

Amendment of the 2003 Directions

2. The 2003 Directions are amended in accordance with paragraphs 3 to 5.

3. In paragraph 1(2)—

(a) in the definition "'recommended by the Institute" ("*a gymeradwyir gan y Sefrdliad*")", after "Technology Appraisal Guidance" insert ", Highly Specialised Technology Guidance or a Recommendation for Use Within the Cancer Drug Fund";

(b) in the definition of "'Technology Appraisal Guidance" ("*Canllawiau Gwerthuso Technoleg*")" for "Technology Appraisal Guidance" ("*Canllawiau Gwerthuso Technoleg*")" substitute "Technology Appraisal Guidance or Highly Specialised Technology Guidance" ("*Canllawiau Gwerthuso Technoleg neu Ganllawiau Technoleg Arbenigol Icavn*")"; and

(c) in the appropriate places in the alphabetical order insert—

"Final Appraisal Determination"
("*Penderfyniad Gwerthuso Ter &noP'*")
means the Institute's appraisal committee's final draft guidance about using a health care intervention in the National Health

(1) As amended by the Directions to Local Health Boards and NHS Trusts in Wales dated 23 December 2003, 4 March 2004, 8 February 2005, 3 April 2006, 25 October 2006, 19 March 2009 and 10 March 2010.

(2) 2009 No. 9.

(3) Established pursuant to section 232 of the Health and Social Care Act 2012 (c. 7).

Service issued in accordance with the Institute's published procedures;" and

"Recommendation for Use Within the Cancer Drugs Fund" ("*Cymeradwyaeth ar gyfer Defnydd o fewn y Gronfa Cyffuriau Caner*") means recommended for use within the Cancer Drugs Fund following appraisals conducted by the Institute in accordance with their published procedures since 29 July 2016;".

4. Save in the case of Technology Appraisal Guidance published before 26 April 2017 and for which paragraph 2 of the 2003 Directions will continue to have effect, paragraph 2 of the 2003 Directions is revoked.

5. Subject to paragraph 4, for paragraph 2 of the 2003 Directions substitute—

"2. Subject to paragraphs 2A, 2B and 3 and unless directed otherwise by the Welsh Ministers, a Local Health Board will in exercising those functions that it has been directed to exercise by the Welsh Ministers(1), apply such of those sums paid to it under section 174(1)(b) of the National Health Service (Wales) Act 2006 as may be required so as to ensure that a health care intervention that is recommended by the Institute in Technology Appraisal Guidance, Highly Specialised Technology Guidance or a Recommendation for use within the Cancer Drug Fund is available:

(a) to be prescribed for any patient on a prescription form for the purpose of a patient's NHS treatment; or

(b) to be supplied or administered to any patient for the purpose of the patient's NHS treatment,

as soon as reasonably practicable and, in any event, within two months of the publication by the Institute of the Final Appraisal Determination in relation to that health care intervention.

2A. For a healthcare intervention that is recommended by the Institute in Highly Specialised Technology Guidance or a Recommendation for Use within the Cancer Drugs Fund before 26 April 2017, the reference in paragraph 2 to "within two months of the publication by the Institute of the Final Appraisal Determination in relation to that

(1) The Local Health Boards (Directed Functions) (Wales) Regulations 2009 (S.1. 2009/1511) (W. 147).

healthcare intervention" is amended to "within two months of 26 April 2017."

2B.—(1) In exceptional circumstances, where the scale of service planning necessary to make a health care intervention available will take longer than two months, the reference in paragraph 2 to two months is amended to three months.

(2) Where a Local Health Board determines that the circumstances in sub-paragraph (1) are satisfied in relation to a health care intervention, it must, within 3 weeks of the publication by the Institute of the Final Appraisal Determination relating to that health care intervention, advise the Welsh Ministers, in writing, of its decision to provide the health care intervention within three months of the publication of the Final Appraisal Determination and its reasons for that decision."

Amendment of the 2009 Directions

6. Save in respect of a medicine recommended by the AWMSG that has been endorsed by the Minister before 26 April 2017, and for which paragraph 2 to the 2009 Directions will continue to have effect, paragraph 2 of the 2009 Directions is revoked.

7. Subject to paragraph 6, for paragraph 2 of the 2009 Directions substitute—

"2. Unless directed otherwise by the Welsh Ministers, and subject to paragraph 2A, a Local Health Board must in exercising its functions, including those functions it has been directed to exercise by the Welsh Ministers(1), apply such amounts of the sums paid to it under section 174(1)(b) of the Act as may be required so as to ensure that a medicine recommended by the AWMSG and endorsed by the Minister is, as soon as reasonably practicable and, in any event, from a date not later than two months from the date of the Minister's endorsement, available:

(a) to be prescribed for any patient on a prescription form for the purpose of the patient's NHS treatment; or

(b) to be supplied or administered to any patient for the purpose of the patient's NHS treatment.


2A.—(1) In exceptional circumstances, where the scale of service planning necessary to make

(1) The Local Health Boards (Directed Functions) (Wales) Regulations 2009 (5.1.2009/1511) (W. 147).

a medicine available will take longer than two months, the reference in paragraph 2 to two months is amended to three months.

(2) Where a Local Health Board determines that the circumstances in sub-paragraph (1) are satisfied in relation to a medicine, it must, within 3 weeks of the date of endorsement by the Minister of that medicine, advise the Welsh Ministers, in writing, of its decision to provide the medicine within three months of the date of the Ministerial endorsement and its reasons for that decision."

Signed

A handwritten signature in black ink, appearing to be 'F. Atherton', written in a cursive style.

Frank Atherton, Chief Medical Officer, Welsh Government, under the authority of the Cabinet Secretary for Health, Well-being and Sport, one of the Welsh Ministers

Date 19 April 2017