

# National Prescribing Indicators 2020–2021

Supporting Information for Prescribers and Healthcare Professionals

February 2020

This document has been prepared by a multiprofessional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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# GLOSSARY

ADQ – average daily quantity ADRs – adverse drug reactions AF – Atrial Fibrillation AKI – Acute Kidnev Iniurv AWMSG - All Wales Medicines Strategy Group AWTTC – All Wales Therapeutics and Toxicology Centre bd - twice-daily CEPP – Clinical Effectiveness Prescribing Programme CKD – chronic kidney disease DDD - defined daily dose DVLA – Driver and Vehicle Licensing Agency eGFR - estimated glomerular filtration rate HCAI - healthcare associated infection MHRA – Medicines and Healthcare products Regulatory Agency MRSA - methicillin-resistant Staphylococcus aureus NICE - National Institute for Health and Care Excellence NPH - neutral protamine Hagedorn NPIs - National Prescribing Indicators NSAIDs - non-steroidal anti-inflammatory drugs PHE – Public Health England PPIs – proton pump inhibitors PU – prescribing unit RCoA - Royal College of Anaesthetists RCGP - Royal College of General Practitioners SSRIs - selective serotonin reuptake inhibitors STAR-PU – specific therapeutic group age-sex related prescribing unit UDG – user-defined group WeMeReC - Welsh Medicines Resource Centre

YCC – Yellow Card Centre

#### NOTES

Implementation of the NPIs does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

#### **1.0 PRIORITY AREAS**

#### 1.1 ANALGESICS

# 1.1.1 Opioid burden

*Purpose*: To encourage the appropriate use and review of all opioids in primary care, minimising the potential for dependence, diversion, misuse and ADRs.

Unit of measure: Opioid burden UDG ADQs per 1,000 patients

#### Why is this important?

- The prescribing of opioids is often not the most appropriate or effective treatment option for patients with chronic pain, and can risk exposing patients to unnecessary harm.
- Despite the lack of evidence for use in chronic non-cancer pain, research has found an escalation of strong opioid prescribing in primary care, predominantly for non-cancer patients.
- Opioid analgesics have well established side effects including constipation, nausea and vomiting, and respiratory depression, and repeated administration may cause tolerance and dependence.
- Concerns about the harms caused by extensive prescribing of opioids have become particularly pertinent as a result of their extensive misuse in the USA.

#### How can changes be made?

- Ensure that when prescribing opioids, consideration is given to: the benefits of treatment; the risks of prescribing, including dependency, overdose and diversion; all prescribed and non-prescribed medicines the person is taking, and whether the person may be opioid naïve.
- If it is thought opioid therapy may play a role in a patient's pain management, a trial should be initiated to establish whether the patient achieves a reduction in pain with the use of opioids – if not they should be stopped.
- Dose escalation should be limited as risk of harm rises as dose increases, especially if there is inadequate relief of pain. Above an oral morphine equivalent daily dose of 120 mg, further benefit is unlikely.
- Use The RCoA Faculty of Pain Medicine checklist to aid discussions regarding opioid treatment with patients.
- Conduct a search to identify patients on an oral morphine equivalent daily dose of ≥120 mg in order to undertake reviews.

#### **Opioid Equivalence Table (Values are approximate – see notes below)**

Reproduced with kind permission from a resource developed by Emma Davies, Advanced Pharmacist Practitioner in Pain Management, Swansea Bay UHB.

Morphine	Oxycodone	Fentanyl	Buprenorphine	Codeine phosphate/ Dihydrocodeine	Tramadol	<b>Tapentadol</b> (Palexia <sup>®</sup> SR)
Oral (mg)	Oral (mg)	Transdermal patch (mcg/hr)	Transdermal patch (mcg/hr)	Oral (mg)	Oral (mg)	Oral (mg)
24hr total dose	24hr total dose	Patch strength STABLE PAIN ONLY	Patch strength STABLE PAIN ONLY	24hr total dose	24hr total dose	24hr total dose
5				60	50	
10			Б	120	100	
15			5		150	
20	10		10	240	200	
30	15		10		300	
40	20	10	20		400	100
60	30	12	25			100
80	40					200
100	50	25	52.5			200
120	60		52.5			300

Doses above this level are not recommended in chronic pain

If patient is still complaining of pain despite opioids at this level, then opioids are not working and should be reduced and stopped even if there is no other treatment available.

140	70	37	37 70			
160	80				400	
180	90	50				400
200	100		50	50		500
240	120	62	105			
280	140	75				
320	160		140			
360	180		140			

Each row is roughly equivalent e.g.: 60 mg bd oral morphine = 30 mg bd oral oxycodone = 25 mcg/hr fentanyl patch

NB: This is to be used as a guide rather than a set of definite equivalences. Some doses suggested may be 'off-licence', but are based on clinical experience. Refer to the <u>Summary of Product</u> <u>Characteristics</u> for further details. Most data on doses are based on single dose studies so it may be less accurate in chronic use where similar data are unavailable. Consider that individual patients may metabolise different drugs at varying rates. The advice is to always calculate doses using morphine as standard and to adjust them to suit the patient and the situation – consider making a reduction in morphine equivalence dose of 20–50% when changing drugs. Caution should be used in renal and hepatic failure. Avoid patch use in unstable pain.

- MHRA Opioids e-learning module
- RCoA Faculty of Pain Medicine (2019) <u>Opioids Aware: Tapering and stopping</u> opioids
- AWMSG (2016) Persistent pain resources
- RCoA Faculty of Pain Medicine (2019) Opioids Aware
- RCoA Faculty of Pain Medicine (2019) <u>Checklist for Prescribers</u>
- WeMeReC (2010) <u>Stopping compound medications containing codeine</u>
- SIGN (2019) SIGN 136. Management of chronic pain

#### 1.1.2 Tramadol

*Purpose*: To encourage appropriate use and review of tramadol in primary care, minimising the potential for dependence, diversion, misuse and ADRs.

#### Unit of measure: Tramadol DDDs per 1,000 patients

#### Why is this important?

- While there is a recognised place in pain management for tramadol, there are concerns regarding abuse, dependence and deaths involving tramadol, in addition to the risks associated with misuse and diversion.
- Tramadol produces analgesia by two mechanisms: an opioid effect and an enhancement of the serotonergic and adrenergic pathways. This unique dualaction pharmacological profile of tramadol increases the risk of adverse effects seen in overdose.
- Hallucinations, confusion and convulsions, as well as rare cases of dependence and withdrawal symptoms, have been reported with tramadol at therapeutic doses.
- Tramadol should be used with caution in patients taking concomitant medicines that can lower the seizure threshold, such as tricyclic antidepressants or SSRIs. The use of tramadol is contra-indicated in uncontrolled epilepsy and in patients receiving, or who have recently discontinued (within the previous two weeks) monoamine oxidase inhibitors.

#### How can changes be made?

- Use the AWMSG Tramadol Shared Decision Making Toolkit with patients when consideration is being given to prescribing tramadol.
- Provide patients with the AWMSG Tramadol Patient Information Leaflet where tramadol is initiated.
- If it is appropriate for a patient's tramadol to be stepped down or stopped, reduce the dose slowly to ensure the patient's safety and to minimise the risk of withdrawal symptoms and/or ADRs. Where physical dependence to tramadol develops, the withdrawal syndrome can be severe, with symptoms typical of opiate withdrawal sometimes accompanied by seizures, hallucinations and anxiety.
- To encourage patient engagement and concordance, a suggested approach would be to reduce the dose at each reduction step, e.g. by one 50 mg dose, and to titrate according to how the patient manages, rather than by setting time limits for the next reduction.
- Carry out the tramadol audit AWMSG Tramadol Educational Resource Materials: Audit Materials.

- AWMSG (2013) Tramadol Educational Resource Materials
- AWMSG (2013) Tramadol Audit Materials
- AWMSG (2013) <u>Tramadol Shared Decision Making Toolkit</u>
- AWMSG (2013) <u>Tramadol Patient Information Leaflet</u>
- AWMSG (2016) Persistent pain resources

#### 1.1.3 Gabapentin and pregabalin

*Purpose*: To encourage the appropriate use and review of gabapentin and pregabalin in primary care, minimising the potential for dependence, diversion, misuse and ADRs.

Unit of measure: Gabapentin and pregabalin DDDs per 1,000 patients

#### Why is this important?

- While there is a recognised place in pain management for gabapentin and pregabalin, there are concerns regarding the risks associated with dependence, diversion and misuse.
- There has been an increase in the number of deaths where gabapentin or pregabalin was mentioned on the death certificate in England and Wales, from 12 deaths registered in 2012 to 196 deaths registered in 2017.

#### How can changes be made?

- Use a pain scale (for example, the Leeds assessment of neuropathic symptoms and signs [LANSS]) to assess whether the patient's pain is neuropathic in nature. This will also assist in determining response to treatment.
- Inform patients that response to drug treatment in neuropathic pain is often inadequate, with no more than 40–60% of people obtaining partial pain relief.
- Once treatment has commenced, NICE recommends early assessment followed by regular reviews to assess and monitor effectiveness including pain control, adverse effects and continued need.
- Reduce and stop the gabapentin or pregabalin if the patient has not shown sufficient benefit within eight weeks of reaching the maximum tolerated dose.
  - Gabapentin can be reduced over a minimum of one week; however, a more gradual dose taper by reducing the daily dose by a maximum of 300 mg every four days allows for emergent symptoms that may have been controlled by gabapentin.
  - Pregabalin can be reduced over a minimum of one week; however, a more gradual dose taper by reducing the daily dose by a maximum of 50–100 mg per week allows observation of emergent symptoms that may have been controlled by pregabalin.
- Exercise caution in prescribing gabapentin or pregabalin for patients with a history of substance abuse.

- The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) Pain Scale
- PrescQIPP (2016) Neuropathic pain: Pregabalin and gabapentin prescribing
- PHE (2014) <u>Advice for prescribers on the risk of the misuse of pregabalin and gabapentin</u>
- AWMSG (2016) Persistent pain resources

# **1.2 ANTICOAGULANTS IN ATRIAL FIBRILLATION**

*Purpose:* To encourage the appropriate use and review of anticoagulants in patients with Atrial Fibrillation (AF).

# Units of measure:

The number of patients diagnosed with AF who:

- 1. Have a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 2 or more who are currently prescribed an anticoagulant as a percentage of all patients diagnosed with AF.
- 2. Are currently prescribed an anticoagulant and have received an anticoagulant review (read codes 8BT3, 6A9, or 66QB) within the last 12 months, as a percentage of all patients diagnosed with AF who are prescribed an anticoagulant.
- 3. Are prescribed antiplatelet monotherapy, as a percentage of all patients diagnosed with AF.

#### Why is this important?

- There are over 75,000 people in Wales with AF, and people living in Wales have the highest prevalence for AF across the UK.
- AF causes around 20% of strokes, however this can be reduced by about two thirds if people are anticoagulated.
- Anticoagulation therapy can help to prevent strokes by reducing the likelihood of a blood clot forming.
- Data from the Sentinel Stoke Audit highlights that 61.1% of patients with known AF prior to admission with a stroke were on anticoagulant medication.
- The review of patients with AF who are taking an anticoagulant is vital to ensure that patients have the opportunity to discuss the choice of suitable anticoagulant with their healthcare professional. These discussions can help improve adherence to treatment.
- Antiplatelet monotherapy is no longer recommended in patients with AF as the risks of taking aspirin outweighs any benefits.

#### How can changes be made?

- Patients with persistent or permanent AF should be assessed for stroke risk using the CHA<sub>2</sub>DS<sub>2</sub>VASc score.
- For patients with a CHA<sub>2</sub>DS<sub>2</sub>VASc of 2 or above, anticoagulation should be offered, taking the patient's bleeding risk into account.
- Review patients on anticoagulation therapy at least annually, or more frequently if clinically relevant events occur affecting anticoagulation or bleeding risk. Patients should have the opportunity to discuss the choice of anticoagulant with their health care professional.
- Antiplatelet medication, i.e. aspirin or clopidogrel, is no longer recommended in patients with AF. However, prescribers should be aware that patients may need to take antiplatelets for other indications.

- AWMSG (2020) <u>All Wales Advice on Oral Anticoagulation for Non-valvular Atrial</u> <u>Fibrillation</u>
- NICE (2014) <u>CG180: Atrial fibrillation: management</u>
- NICE (2014) CG180: Patient decision aid and user guide
- <u>Stop a Stroke website</u>

# **1.3 ANTIMICROBIAL STEWARDSHIP**

#### **1.3.1 Total antibacterial items**

*Purpose*: To encourage the appropriate prescribing of all antibiotics in primary care.

#### Units of measure:

Total antibacterial items per 1,000 STAR-PUs.

# Why is this important?

• The widespread and often excessive usage of antimicrobials in one of the main factors contributing to the increasing emergence of antimicrobial resistance.

# How can changes be made?

- Follow local or national guidelines, prescribing antibiotics for the shortest effective course at the most appropriate dose.
- Consider the risk of antimicrobial resistance for individual patients and the population as a whole.
- Document the clinical diagnosis (READ/SNOMED code to aid audit) and reason for prescribing, or not prescribing, an antimicrobial.
- Consider a delayed/back up prescription.
- Provide patients with leaflets/resources so they are aware of how long they can expect their condition to last and how they can self-care. Resources are available in the TARGET Antibiotics toolkit.
- Carry out the AWMSG National Audit: Focus on Antibiotic Prescribing.

- AWMSG (2015) Primary care antimicrobial guidelines
- AWMSG (2013) <u>CEPP National Audit: Focus on Antibiotic Prescribing</u>
- WeMeReC (2012) Bulletin: Appropriate antibiotic use whose responsibility?
- RCGP TARGET Antibiotics toolkit

#### 1.3.2 4C antimicrobials

**Purpose:** To reduce the prevalence of HCAI including *Clostridioides difficile* infection and *Staphylococcus aureus* bacteraemia caused by MRSA by encouraging a reduction in variation and reduce overall prescribing of the 4C antimicrobials (co-amoxiclav, cephalosporins, fluoroquinolones and clindamycin) in primary care.

#### Unit of measure:

4C items combined, per 1,000 patients.

#### Why is this important?

- The use of simple generic antibiotics and the avoidance of broad-spectrum antibiotics (e.g. co-amoxiclav, cephalosporins, fluoroquinolones and clindamycin) preserve these from resistance and reduce the risk of *C. difficile*, MRSA and resistant urinary tract infections.
- Compared with narrow-spectrum antibiotics, broad-spectrum antibiotics are more likely to significantly change the gut flora, potentially allowing other bacteria, such as *C. difficile*, to become established.
- The most commonly implicated antibiotics in *C. difficile* infection include clindamycin, cephalosporins, fluoroquinolones and co-amoxiclav.

#### How can changes be made?

- Follow local or national guidelines, prescribing antibiotics for the shortest effective course at the most appropriate dose.
- Consider the risk of antimicrobial resistance for individual patients and the population as a whole.
- Document the clinical diagnosis (READ/SNOMED code to aid audit) and reason for prescribing, or not prescribing, an antimicrobial.
- Consider a delayed/back up prescription.
- Provide patients with leaflets/resources so they are aware of how long they can expect their condition to last and how they can self-care. Resources are available in the TARGET Antibiotics toolkit.
- Carry out the AWMSG National Audit: Focus on Antibiotic Prescribing.

- AWMSG (2015) <u>Primary Care Antimicrobial Guidelines</u>
- AWMSG (2013) CEPP National Audit: Focus on Antibiotic Prescribing
- WeMeReC (2012) <u>Bulletin: Appropriate antibiotic use whose responsibility?</u>
- RCGP <u>TARGET Antibiotics toolkit</u>

# 2.0 SUPPORTING DOMAINS

# 2.1 SAFETY

# 2.1.1 Prescribing Safety Indicators

*Purpose:* To identify patients at high risk of adverse drug reactions and medicines-related harm in primary care.

#### Units of measure:

#### Prescribing Safety Indicators related to Acute Kidney Injury (AKI)

- Number of patients on the CKD register (CKD stage 3–5) who have received a repeat prescription for an NSAID within the last 3 months.
- Number of patients who are not on the CKD register but have an eGFR of < 59 ml/min and have received a repeat prescription for an NSAID within the last 3 months.
- Number of patients with concurrent prescriptions of an NSAID, renin-angiotensin system (RAS) drug and a diuretic.
- Number of patients aged 75 and over with a current prescription for an ACE Inhibitor or loop diuretic without a check of renal function and electrolytes in the previous 15 months.

#### Prescribing Safety Indicators related to bleeds

- Number of patients with a peptic ulcer who have been prescribed NSAIDs without a PPI.
- Number of patients with concurrent prescriptions of warfarin and an oral NSAID.
- Number of patients with concurrent prescriptions for a DOAC and an oral NSAID.
- Number of patients aged 65 years or over prescribed an NSAID plus aspirin and/or clopidogrel but without gastroprotection (PPI or H<sub>2</sub> receptor antagonist).
- Number of patients with concurrent prescriptions of an oral anticoagulant (warfarin or DOAC) and an SSRI.

#### Prescribing Safety Indicators related to cognition

- Number of patients aged 65 years or over prescribed an antipsychotic.
- Number of patients aged 75 and over with an Anticholinergic Effect on Cognition (AEC) score of 3 or more for items on active repeat.

#### **Prescribing Safety Indicators specific to females**

- Number of female patients with a current prescription of oestrogen-only hormone replacement therapy (HRT) without any hysterectomy READ/SNOMED codes.
- Number of female patients with a past medical history of venous or arterial thrombosis who have been prescribed combined hormonal contraceptives.
- Number of female patients aged 14–45 with a prescription for sodium valproate.
- Number of female patients aged 14-45 with a prescription for oral retinoids.

#### Prescribing Safety Indicators related to 'other'

- Number of patients under 16 with a current prescription of aspirin.
- Number of patients with asthma who have been prescribed a beta-blocker.
- Number of patients with concurrent prescriptions of verapamil and a beta-blocker.

s this important?
This NPI is facilitating the move towards a more patient-focussed approach considering whether the right patients are getting the right medicines. This is intended to reduce the number of ADRs experienced by patients. In the UK, it is estimated that up to around 6.5% of hospital admissions are related to ADRs. ADRs can often be predictable, making it possible to identify potential causes and address them before actual patient harm occurs. Therefore a process of identifying patients electronically could enable intervention and help avoid harm. The PINCER study demonstrated that such an approach is an effective method for reducing the frequency of a range of medication errors.
an changes be made?
Review patients identified as being at high risk of ADRs and medicines-related harm ensuring that action taken is clearly documented and coded appropriately.
resources are available?
AWMSG (2018) Antipsychotics in dementia audit MHRA (2014) Antipsychotics learning module WeMeReC (2015) Medicines-related admissions PrescQIPP (2016) Bulletin 140: Anticholinergic drugs AWMSG (2015) CEPP All Wales Audit: Towards Appropriate NSAID Prescribing AWMSG (2017) CEPP National Audit: Medicines Management for CKD South London and Maudsley NHS Foundation Trust (2017) Medichec: The Anticholinergic Effect on Cognition Tool (Android Medichec app available, app for iOS due out shortly) Sanofi (2018) Guide for healthcare professionals: Information on the risks of valproate ▼ use in girls (of any age) and women of childbearing potential

# 2.1.2 Proton pump inhibitors

*Purpose*: To encourage appropriate use of proton pump inhibitors (PPIs) in primary care.

# Unit of measure: PPI DDDs per 1,000 PUs

# Why is this important?

- Safety concerns associated with long-term PPI use have been raised, e.g. *C. difficile* infection, fractures and hypomagnesaemia.
- Other possible serious adverse effects include acute interstitial nephritis, vitamin B<sub>12</sub> deficiency and rebound acid hypersecretion syndrome.

# How can changes be made?

- When initiating a PPI, only consider for short courses (4 weeks) where needed, using acute, rather than repeat, prescriptions.
- Review long-term PPI prescriptions at least annually, and advise patients that it may be appropriate for them to return to self-treatment with antacid and/or alginate therapy.
- Inform patients of the potential long-term effects of PPIs as this may result in them being more willing to try self-care to improve their symptoms.
- Use the AWMSG patient information leaflet 'Stopping Your PPI' when initiating; reducing and stopping PPIs.
- Use the PPI audit and review toolkit in AWMSG Safe Use of Proton Pump Inhibitors resource pack.

- AWMSG (2018) <u>Safe Use of Proton Pump Inhibitors</u>
- WeMeReC (2015) Proton pump inhibitors bulletin
- PrescQIPP (2015) Bulletin 92: Safety of long term PPIs
- WeMeReC (2010) Stopping Medicines Proton Pump Inhibitors

# 2.1.3 Hypnotics and anxiolytics

*Purpose*: To encourage a reduction in the inappropriate prescribing of hypnotics and anxiolytics in primary care.

#### Unit of measure: Hypnotic and anxiolytic UDG ADQs per 1,000 STAR-PUs

#### Why is this important?

- There is a high level of hypnotic and anxiolytic prescribing in NHS Wales, compared with England.
- The problems associated with benzodiazepines (e.g. tolerance, dependence, withdrawal causing rebound insomnia) are well known, and the number of deaths associated with benzodiazepines has increased.
- Hypnotics and anxiolytics are known to significantly increase the risk of falls.

#### How can changes be made?

- Consider hypnotics only after non-drug therapies have been explored.
- When prescribing hypnotics, use the lowest dose possible, for the shortest duration possible and in strict accordance with their licensed indications: no more than 4 weeks.
- Do not offer benzodiazepines for the treatment of generalised anxiety disorder except as a short-term measure during crises.
- Always consider reducing hypnotics and anxiolytics where appropriate.
- Carry out the hypnotic and anxiolytic audit from the AWMSG Educational Pack: Materials to Support Appropriate Prescribing of Hypnotics and Anxiolytics across Wales.
- Use the hypnotic and anxiolytic reduction/withdrawal resources in the AWMSG Educational Pack: Materials to Support Appropriate Prescribing of Hypnotics and Anxiolytics across Wales.

- AWMSG (2016) Educational Pack: Material to Support Appropriate Prescribing of <u>Hypnotics and Anxiolytics across Wales</u>
- WeMeReC (2015) Bulletin: Sedative medicines in older people
- AWMSG (2014) Polypharmacy: Guidance for Prescribing
- WeMeReC (2009) <u>Stopping Medicines benzodiazepines</u>

#### 2.1.4 Yellow Cards

*Purpose:* To encourage an increase in the number of Yellow Cards submitted in Wales.

*Unit of measure*: Number of Yellow Cards submitted per GP practice, per health board and per hospital.

Number of Yellow Cards submitted by Community Pharmacies, per health board.

# Why is this important?

- ADRs are a significant clinical problem, increasing morbidity and mortality.
- The Yellow Card Scheme is vital in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for those that use them.
- Yellow Card reporting supports the identification and collation of ADRs, which might not have been known about before.

#### How can changes be made?

- Yellow Card reports can be completed:
  - Online: www.mhra.gov.uk/yellowcard
  - Using the free Yellow Card app
  - Through the Vision prescribing system.
  - By writing to FREEPOST YELLOW CARD
  - By emailing: <u>yellowcard@mhra.gov.uk</u>
  - By downloading forms from the website
- You only need to suspect that an adverse drug reaction was caused by a medicine to report it.
- Don't assume someone else will report an adverse drug reaction you witness.
- Reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market.
- Sign up to make a <u>Yellow Card Support Pledge</u> and encourage colleagues and patients/carers to do the same.

- Yellow Card champions are available in each health board to provide training. Contact <u>YCCWales@wales.nhs.uk</u> for more information
- Health Education Improvement Wales <u>e-learning modules on Yellow Card</u>
   <u>Scheme</u>
- Yellow Card reports can be completed online <u>Yellow Card website</u>
- Health Professional Guidance on Reporting
- MHRA web pages
- WeMeReC (2013) Pharmacovigilance Bulletin
- <u>YCC Wales website</u>
- The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) e-learning module: <u>Adverse Drug Reactions: Reporting makes</u> <u>medicines safer</u>

#### **2.2 EFFICIENCIES**

#### 2.2.1 Best value biological medicines

Purpose: To ensure prescribing of biological medicines supports cost-efficient prescribing in primary and secondary care in Wales.

Unit of measure: Quantity of biosimilar medicines prescribed as a percentage of total 'reference' product plus biosimilar.

#### Why is this important?

- Biological medicines account for a significant expenditure in NHS Wales. •
- Biosimilar medicines are biological medicines that have been developed as highly similar and clinically equivalent to their 'reference' or 'originator' medicine.
- A number of reference biological medicines have recently lost their patent • protection, or will lose it within the next five years, creating opportunities for increased commercial competition.
- Although individual health boards' contracting prices, as well as national contracting prices, for biosimilar and reference medicines may vary, there are expected to be significant cost-saving opportunities from the use of the most costefficient biological medicine.

#### How can changes be made?

- Where AWMSG or NICE has recommended the reference medicine, the same • guidance will normally apply to the biosimilar.
- At the time of dispensing there must not be automatic substitution of the reference product with a biosimilar medicine. Therefore, the clinician in consultation with the patient should make the decision on whether the reference or biosimilar biological medicine will be prescribed for the patient.
- All biological medicines, including biosimilars, must be prescribed by brand name. •
- Current biological medicines with biosimilar versions for use in NHS Wales that will be reported on for the NPI in 2020-2021 are:
  - Infliximab Inflectra®▼ \_
  - Etanercept Benepali®▼, Erelzi®▼
  - Rituximab Truxima<sup>®▼</sup>
  - Trastuzumab Ontruzant®▼
  - Adalimumab Amgevita<sup>®</sup>▼, Hulio<sup>®</sup>▼, Hyrimoz<sup>®</sup>▼, Imraldi<sup>®</sup>▼ Teriparatide Movymia<sup>®</sup>▼, Terrosa<sup>®</sup>▼

- AWTTC (2019) SPIRA Biosimilar Efficiencies •
- European Medicines Agency (2017) Biosimilars in the EU •
- European Commission (2016) What I need to know about Biosimilar Medicines: • Information for patients
- NHS England (2019) What is a biosimilar medicine? •
- The Cancer Vanguard (2017) Biosimilars frequently asked questions for • healthcare professionals
- AWMSG Position statement for biosimilar medicines •
- NICE Position statement for biosimilar medicines •
- NICE (2018) Key Therapeutic Topic 15: Biosimilar medicines •
- MHRA (2008) Drug Safety Update. Biosimilar products •
- The Cancer Vanguard Biosimilars adoption resources

# 2.2.2 Insulin

*Purpose:* To encourage a reduction in the prescribing of long-acting insulin analogues in primary and secondary care in line with NICE guidance to maximise cost-effectiveness in Wales.

**Unit of measure:** Items/number of long-acting insulin analogues as a percentage of total long- and intermediate-acting insulin prescribed.

#### Why is this important?

- In type 2 diabetes mellitus when blood glucose control is inadequate on oral antidiabetic therapy, insulin should be considered as the next treatment option.
- Human isophane (NPH) insulin is recommended as the first choice regimen.
- There is an absence of evidence to suggest superiority of the long-acting insulin analogues over NPH insulin.

#### How can changes be made?

- Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Discuss with the patient the comparative effectiveness of the specific insulin types and ascertain any preference.
- When patients are started on an insulin therapy, a structured programme of active dose titration should be employed. In addition, this programme should also cover injection technique, continuing telephone support, self-monitoring, dietary understanding, DVLA guidance, management of hypoglycaemia, management of acute changes in plasma glucose control, and support from an appropriately trained and experienced healthcare professional.

- NICE (2015) NG28: Type 2 diabetes in adults: management
- Cochrane (2007) Long-acting analogues versus NPH insulin
- AWTTC (2019) <u>Best Practice Day 2019 Presentation by Lindsay George:</u> <u>Prudent prescribing of human versus analogue insulin (YouTube)</u>

#### 2.2.3 Low value for prescribing

**Purpose:** To drive a reduction in the prescribing of items considered as not suitable for routine prescribing in Wales.

Unit of measure: Low value for prescribing UDG spend per 1,000 patients.

#### Why is this important?

- Prescribing expenditure accounts for nearly 6% of total Welsh Government expenditure.
- Aim of this initiative is to minimise the prescribing of items that offer a limited clinical benefit to patients where more cost effective options may be available.

#### How can changes be made?

- The Low Value for Prescribing in NHS Wales initiative papers provide guidance to clinicians and health boards in Wales.
- Prescribers are expected to have due regard for this advice when deciding whether or not to prescribe any of the included items.
- Changes to individual medication regimens should be in partnership with patients and where appropriate carers, with the prescriber able to exercise their clinical discretion in determining what is most appropriate for each individual patient.

- AWMSG (2019) Medicines Identified as Low Priority for Funding paper 1
- AWMSG (2018) Medicines Identified as Low Priority for Funding paper 2
- AWTTC (2019) <u>SPIRA Low Value for Prescribing dashboard</u>
- AWMSG (2020) <u>Items Identified as Low Value for Prescribing in NHS Wales –</u> paper 3