



# National Prescribing Indicators 2022–2025

Supporting Information for Prescribers and Healthcare Professionals

#### February 2022

(January 2023 – 'Best value biological medicines' section updated with bevacizumab removed from basket of included medicines)

(October 2023 – Document updated to reflect that the 2022–2023 NPIs have been extended to 2022–2025

(August 2024 – Analgesics section updated with new oral morphine equivalence measure for opioid burden and high strength opioids)

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 Kidney Injury

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

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

OME – oral morphine equivalence

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

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.

This document was originally published in February 2022 to set out supporting information for the National Prescribing Indicators 2022–2023. However, in September 2022, AWMSG agreed that the review and update of the NPIs should change from annually, to every three years. This change will enable health boards to develop longer term plans for utilising the NPIs, by providing assurance that indicators will be in place for a minimum of three years. As a result of this the 2022–2023 National Prescribing Indicators were subsequently extended and will be referred to as the 2022–2025 National Prescribing Indicators throughout this document.

# 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.

#### Units of measure 2022-2025:

#### 2022-2023

- 1. Opioid burden UDG ADQs per 1,000 patients
- 2. High strength opioids UDQ ADQs per 1,000 patients

#### 2023-2024:

- 1. Opioid burden UDG DDDs per 1,000 patients
- 2. High strength opioids UDQ DDDs per 1,000 patients

#### 2024-2025:

- 1. Opioid burden UDG total oral morphine equivalence (OME) per 1,000 patients.
- 2. High strength opioids UDG with a likely daily dose of ≥120mg oral morphine equivalence (OME) per 1,000 patients

# Why is this important?

- Due to a lack of evidence of effectiveness, opioids are not recommended as a treatment option for the management of chronic primary pain
- 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?

- NICE guidance states that opioids should not be initiated for the management of chronic primary pain
- Patients prescribed opioids for chronic primary pain should be reviewed as part of shared decision making.
- 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.

- NICE (2021) NG193: Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain.
- MHRA Opioids e-learning module
- RCoA Faculty of Pain Medicine (2019) <u>Opioids Aware: Tapering and stopping opioids</u>
- AWMSG (2022) Resources for pharmacological management of pain
- RCoA Faculty of Pain Medicine (2019) Opioids Aware
- RCoA Faculty of Pain Medicine (2019) <u>Checklist for Prescribers</u>

# Oral Morphine Equivalence (OME)

BNF Chemical Substance Name	Relative potency to oral morphine*†	References
Buprenorphine sublingual tablets	60	PCG
Buprenorphine transdermal patch	100	PCG
Butorphanol nasal spray	7	PME
Co-codamol (codeine phos/paracetamol) oral	0.1	PCG
Codeine phosphate oral	0.1	PCG
Co-dydramol oral	0.1	PCG
Dextromoramide tartrate	4	OPN
Dextropropoxyphene	0.1	OPN
Diamorphine hydrochloride oral	1	OPN
Dihydrocodeine tartrate oral	0.1	PCG
Dipipanone hydrochloride oral	0.5	CHF
Fentanyl oromucosal lozenge	130	PME
Fentanyl transdermal patch	100	BNF
Fentanyl oromucosal tablet	130	PME
Fentanyl intra-nasal spray	160	PME
Fentanyl oromucusol film	180	PME
Hydromorphone hydrochloride oral	5	BNF
Levorphanol tartrate oral	11	PME
Meptazinol hydrochloride oral	0.04	CHF
Methadone hydrochloride oral	4	CHF
Morphine hydrochloride oral	1	OPN
Morphine hydrochloride suppository	1	PCG
Morphine sulphate oral	1	PCG
Oxycodone hydrochloride oral	1.5	BNF
Papaveretum	1	OPN
Pentazocine hydrochloride oral	0.37	OPN
Pentazocine lactate	0.37	OPN
Pethidine hydrochloride oral	0.125	CHF
Phenazocine hydrobromide	4	OPN
Tapentadol hydrochloride oral	0.4	FPM
Tramadol hydrochloride oral	0.1	PCG

BNF: <u>British National Formulary</u>; CHF: <u>Cheshire Formulary</u>; FPM: <u>Faculty of Pain Medicine of the Royal College of Anaesthetists</u>; PME: <u>Pain Management Education at UCSF</u>; OPN: <u>Open Prescribing</u>; PCG: <u>Palliative Care Guidelines (traditional)</u>

<sup>\*</sup> Relative potency to oral morphine values have been discussed at Welsh Pharmacy Pain Group.

<sup>&</sup>lt;sup>†</sup> There is no universal agreement, or national or internationally recognised consensus, for these values as there is no mechanism by which they can be determined. Values are based on national and international opinion and have been taken from what are believed to be the most robust sources, with an emphasis on UK sources reflective of UK practice where available.

#### 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?

- Tramadol is licensed for the treatment of moderate to severe pain. However, the NICE guideline NG193 recommends that opioids, including tramadol, are not initiated for chronic primary pain.
- 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?

- 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.
- Conduct an audit AWMSG Tramadol educational resources: Primary care tramadol audit.

- AWMSG (2021) Tramadol educational resources
- AWMSG (2022) Resources for pharmacological management of pain

#### 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
- AWMSG (2022) Resources for pharmacological management of pain
- PrescQIPP (2021) Neuropathic pain (log in required for access)
- PHE (2014) <u>Advice for prescribers on the risk of the misuse of pregabalin and gabapentin</u>
- SIGN (2019) SIGN 136. Management of chronic pain

#### 1.2 Anticoagulation 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 Stroke 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.

- NICE (2021) NG196: Atrial fibrillation: diagnosis and management
- AWMSG (2020) <u>All Wales Advice on Oral Anticoagulation for Non-valvular Atrial</u> Fibrillation updated guideline due for publication early 2022.
- NICE (2018) Quality Standard Atrial Fibrillation
- All Wales Cardiac Network Sharepoint (registration required)

#### 1.3 Antimicrobial stewardship

#### 1.3.1 Total antibacterial items

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

#### Unit 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) <u>Primary care antimicrobial guidelines</u> update due for publication early 2022
- AWMSG (2013) <u>CEPP National Audit: Focus on Antibiotic Prescribing</u> update due for publication early 2022
- 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> update due for publication early 2022
- AWMSG (2013) <u>CEPP National Audit: Focus on Antibiotic Prescribing</u> update due for publication early 2022
- RCGP TARGET Antibiotics toolkit

#### 1.4 Decarbonisation of inhalers

**Purpose:** To encourage an increase in the use of low Global Warming Potential (GWP) inhalers (dry powder inhalers (DPI) and soft mist inhalers (SMI), to reduce the carbon footprint of inhaler prescribing in Wales.

#### Unit of measure:

The number of DPIs and SMIs as a percentage of all inhalers prescribed.

# Why is this important?

- The hydrofluorocarbon (HFC) gasses used as propellants in MDIs are estimated to be responsible for 4% of the entire carbon footprint of the NHS.
- DPIs have a carbon footprint 18 times lower than MDIs.
- SMIs do not contain a propellant, therefore have a lower carbon footprint than MDIs.

# How can changes be made?

- Ensure a DPI is considered when a new inhaler is commenced and during respiratory reviews.
- Recommend low carbon alternatives to patients currently using MDIs.
- Where patients are using several classes of inhalers and poor technique is identified with one device, ensure that a DPI is prioritised.
- Ensure that changes only take place where the patient is able to use a new device safely.

- AWTTC (2022) <u>SPIRA Decarbonisation Dashboard</u> (NHS Wales network connection required)
- AWMSG (2021) All Wales Asthma Diagnosis and Management Guidelines
- AWMSG (2021) All Wales COPD Management and Prescribing Guidelines
- NICE (2020) Patient decision aid: Inhalers for asthma

# 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.</li>
- 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 14–55 with a prescription for sodium valproate.
- Number of female patients aged 14-55 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.

# Why is 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.

# How can 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.

- AWMSG (2023) <u>Polypharmacy in older people: A guide for healthcare</u> professionals
- PrescQIPP (2020) <u>Bulletin 253: Anticholinergic burden</u> (log in required for access)
- Sanofi (2020) <u>Guide for healthcare professionals: Information on the risks of</u> valproate ▼ use in girls (of any age) and women of childbearing potential
- AWMSG (2018) CEPP National Audit: Antipsychotics in dementia audit
- South London and Maudsley NHS Foundation Trust (2017) <u>Medichec: The Anticholinergic Effect on Cognition Tool</u> (Android and iOS Medichec apps available)
- AWMSG (2017) CEPP National Audit: Medicines Management for CKD
- AWMSG (2015) <u>CEPP All Wales Audit: Towards Appropriate NSAID</u> Prescribing
- MHRA (2014) <u>Antipsychotics e-learning module</u>

# 2.1.2 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 (2021) <u>Material to Support Appropriate Prescribing of Hypnotics and</u> Anxiolytics across Wales
- Bruyère Research Institute (2019) <u>Benzodiazepine & Z-Drug (BZRA)</u>
   Deprescribing Algorithm
- AWMSG (2023) <u>Polypharmacy in older people: A guide for healthcare professionals</u>

#### 2.1.3 Yellow Cards

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

**Units 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: yellowcard@mhra.gov.uk
  - 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.

#### What resources are available?

- Yellow Card champions are available in each health board to provide training.
   Contact <u>YCCWales@wales.nhs.uk</u> for more information
- Yellow Card reports can be completed online Yellow Card website
- Health Education Improvement Wales <u>e-learning module on Yellow Card Scheme</u>
- Health Professional Guidance on Reporting
- YCC Wales website
- MHRA website
- NHS Education for Scotland e-learning modules on ADRs

#### **Download the Yellow Card App:**

- Android
- Apple

#### 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 cost-efficient 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.
- The list of biological medicines being reported on will be determined by the requirements of the service. For 2022-2025 this will be focused on the biological medicines where a biosimilar version has recently become available. However, there will continue to be monitoring of an overall basket of biological medicines which will include:
  - Infliximab Flixabi<sup>®</sup>, Inflectra<sup>®</sup>, Remsima<sup>®</sup>, Zessly<sup>®</sup>
  - Etanercept Benepali<sup>®</sup>, Erelzi<sup>®</sup>
  - Rituximab Rixathon<sup>®</sup>

    ▼, Ruxience<sup>®</sup>

    ▼, Truxima<sup>®</sup>

    ▼

  - Trastuzumab Herzuma<sup>®</sup>, Ontruzant<sup>®</sup>, Trazimera<sup>®</sup>, Zercepac<sup>®</sup>
     Adalimumab Amgevita<sup>®</sup>, Hyrimoz<sup>®</sup>, Idacio<sup>®</sup>, Imraldi<sup>®</sup>, Yuflyma<sup>®</sup>
     Ranibizumab Ongavia<sup>®</sup>

- AWMSG (2023) <u>Maximising the opportunity presented by biosimilar medicines</u> A national strategy for Wales
- AWTTC (2021) <u>SPIRA Biosimilar Efficiencies</u> (NHS Wales network connection required)
- AWTTC (2019) Biosimilar Best Practice Day
- NHS England (2019) What is a biosimilar medicine?
- AWMSG (2019) Position statement for biosimilar medicines
- European Medicines Agency (2018) European public assessment reports
- NICE (2018) Key Therapeutic Topic 15: Biosimilar medicines
- The Cancer Vanguard (2017) <u>Biosimilars frequently asked questions for healthcare professionals</u>
- MHRA (2008) <u>Drug Safety Update</u>. <u>Biosimilar products</u>
- NICE Position statement for biosimilar medicines
- The Cancer Vanguard Biosimilars adoption resources

#### 2.2.2 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 (2017) <u>Medicines Identified as Low Priority for Funding paper 1</u>
- AWMSG (2018) Medicines Identified as Low Priority for Funding paper 2
- AWMSG (2020) <u>Items Identified as Low Value for Prescribing in NHS Wales paper 3</u>
- AWTTC (2021) <u>SPIRA Low Value for Prescribing dashboard</u> (NHS Wales network connection required)