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Medicine treatment breaks

This bulletin considers medication that is associated with treatment breaks, also known as drug holidays. This includes antidepressants, bisphosphonates, proton pump inhibitors, hypnotics, topical corticosteroids, medication for attention deficit hyperactivity disorder (ADHD), managing chronic pain and urinary incontinence. This bulletin does not cover temporary breaks for acute conditions, for example acute kidney injury and sick day rules, for this, refer to PrescQIPP bulletin 260: Acute kidney injury - sick day guidance. The bulletin provides suggestions for commissioning organisations and clinicians to assist in reviewing drug treatments and considering treatment breaks. Refer to existing resources for comprehensive information on how to safely stop, discontinue or withdraw a medicine and issues to ensure shared decision making takes place.

The current evidence and resource base largely relates to deprescribing. It is considered that the principles of good practice in deprescribing will be applicable to good practice in implementing treatment breaks.

Contents

Recommendations

- There are some medicines where a treatment break can be beneficial. Ensure that patients prescribed these medicines are flagged for a medication review at appropriate intervals.
- Encourage a systematic and proactive approach to implement medicine treatment breaks appropriately.
- Implement planned periods of discontinuation or reduction in dosage with the intention of evaluating treatment effectiveness, minimising side effects, preventing tolerance and reducing long term effects or harm. This will improve patient safety and quality of life.
- Ensure a patient centred approach to medicine treatment breaks addressing patient's concerns and expectations to identify what really matters to them.
- Proactively identify patients suitable for medicine treatment breaks during medication reviews which identify multiple drug-related problems, adverse reactions, and lack of effectiveness.
- Use deprescribing algorithms to assist in implementing medicine treatment breaks in consultation with individual patients. Refer to the PrescQIPP deprescribing algorithms.

Introduction

Definition

A treatment break, also referred to as a drug holiday is an agreed cessation of medication for a period of time. NICE provides recommendations on drug holidays specifically for ADHD medication.[1]

Of note, is that the term "deprescribing" refers to a systematic and proactive process of medication withdrawal, supervised by a health care professional, with the goal of managing polypharmacy and improving outcomes. This can include a comprehensive review of a patient's medication list and systematically discontinue or reduce the dose of medications with an unfavourable balance of benefits and harms or lack of evidence on long term benefits.[2] Deprescribing is intended to be finite whereas treatment breaks are temporary. It is considered that good practice in deprescribing will be applicable to good practice in implementing treatment breaks.

Why initiate a treatment break

The overall goal of treatment breaks is to improve patient important outcomes taking into account what really matters to the person taking the medicine. These include for example, reducing the overall medication burden, reducing the risk of adverse events, and improving health outcomes such as reducing hospitalisation and mortality. Ultimately, all these goals relate to improving quality of life.[2]

Advantages of treatment breaks

The aim is to ensure planned periods of discontinuation (through appropriate use of deprescribing algorithms) with the intention of improving patient safety and quality of life by:

- Reducing long term effects or harm
- Reducing the risk of side effects resulting in hospitalisation or mortality
- Reducing or preventing tolerance
- Re-assessing treatment effectiveness
- Reducing medication burden.[2,3,4]

There may also be the potential to reduce medication costs.

Potential disadvantages of treatment breaks

- Return of symptoms
- Disease flare or activity
- Withdrawal effects
- Increased monitoring requirements
- Increase healthcare professional workload due to the need to tailor and evaluate the treatment break for the individual.

Drugs or conditions potentially suitable for treatment breaks

The following medicines may be considered for treatment breaks: antidepressants, bisphosphonates, proton pump inhibitors, hypnotics, medication for attention deficit hyperactivity disorder (ADHD), chronic pain management and urinary incontinence. Practical considerations for treatment breaks are outlined in the following sections alongside the potential advantages and disadvantages of a treatment break which may support shared decision making with patients on whether a treatment break is suitable for them.

Osteoporosis treatments - bisphosphonates

The optimal duration of bisphosphonate therapy is unclear and there are possible side effects of long term treatment.[5] Treatment recommendations (described below) vary from three to ten years for oral bisphosphonates and three to six years for intravenous zoledronic acid depending on level of fracture risk.[6] A medication review for people having long term bisphosphonate therapy gives the opportunity to consider whether continuing treatment is the best option, based on the benefits and potential risks or if treatment should be changed or stopped. The response to treatment may also be evaluated to help determine whether to continue treatment.[5]

Recommendations for the duration of bisphosphonate treatment for osteoporosis were updated by the National Osteoporosis Guideline Group (NOGG) in 2021.[6] NICE TA464 which covers Bisphosphonates for treating osteoporosis (last updated 2019) says treatment may be recommended for up to 60 months and NICE CG146 about Osteoporosis: assessing the risk of fragility fracture, does not mention duration of treatment.[7,8] Development of a new NICE clinical guideline titled Osteoporosis: risk assessment, treatment, and fragility facture prevention is underway that will update and replace NICE CG146. The final scope includes the timing and duration of bisphosphonate drug treatment breaks, if needed.[9]

Currently, NICE recommends that adults who have been taking zoledronic acid for three years or alendronate, ibandronate or risedronate for five years should have a review of the need for continuing treatment.[8]

The NOGG strong recommendations are:[6]

- To reassess fracture risk after at least five years for alendronate, ibandronate and risedronate; and at least three years for intravenous (iv) zoledronic acid. Longer durations of treatment, for at least ten years (six years for iv zoledronic acid), are recommended in the following men and women who have a high risk of osteoporotic fragility fracture:
  - Age ≥70 years at the time that the bisphosphonate is started.
  - Who have a previous history of a hip or vertebral fracture(s).
  - Treated with oral glucocorticoids ≥7.5mg prednisolone/day or equivalent.
  - Who experience one or more fragility fractures during the first five years (three years for zoledronic acid) of treatment (if treatment is not changed).[6]
- To stop the bisphosphonate if risk outweighs benefits, use the NICE decision support tool to discuss with the patient and if T-score >-2.5 and BMD and fracture risk (using FRAX) have been re-assessed.[7]
- If a new fracture occurs after bisphosphonate treatment is discontinued, reassess using FRAX and restart treatment.[6]

- If bisphosphonate treatment is discontinued and no new fracture occurs, reassess using FRAX after 18 months for risedronate and ibandronate, two years for alendronate, and three years for zoledronate to inform whether treatment should be restarted.[6]

SIGN clinical guideline 142 recommends that:

- Alendronic acid may be continued for up to ten years in postmenopausal women with osteoporosis, especially those that are at high risk of vertebral fracture.
- Risedronate may be continued for up to seven years in postmenopausal women with osteoporosis.
- Zoledronic acid (5mg, intravenously) annually for three years is recommended in postmenopausal women with osteoporosis. The clinical benefit of annual zoledronic acid in preventing fractures beyond three years is uncertain.[10]

The BNF and NOGG state that there is no evidence for bisphosphonate treatment beyond ten years; management of these patients should be on a case-by-case basis with specialist input as appropriate.[6,11]

The NICE guideline on multimorbidity: clinical assessment and management [NG56] published in 2016 states that when reviewing medicines in people with multimorbidity, tell a person who has been taking a bisphosphonate for osteoporosis for at least three years that there is no consistent evidence of:

- Further benefit from continuing bisphosphonate for another three years
- Harms from stopping bisphosphonate after three years of treatment.

Discuss stopping bisphosphonate after three years and include patient choice, fracture risk and life expectancy in the discussion.

A summary of bisphosphonate review and treatment lengths is provided in table 1.

Table 1. Bisphosphonate summary of recommended treatment lengths in national guidelines

Bisphosphonate	NICE[12] recommended treatment length (years)	SIGN[10] recommended treatment length (years)	NOGG[6]/BNF[11] recommended treatment length (years)	Multimorbidity NICE NG56
Zoledronic acid	3	3	3 to 6	3
Alendronate	5	10	5 to 10	3
Ibandronate	5	Not stated	5 to 10	3
Risedronate	5	7	5 to 10	3

Advantages and disadvantages of a bisphosphonate treatment break

Possible **advantages** of a bisphosphonate treatment break is the potential to reduce side effects or the risk of side effects associated with bisphosphonates, for example:

- Osteonecrosis of the jaw (ONJ).[6,11] Healthcare professionals should consider the following risk factors when evaluating an individual's risk of developing ONJ: Potency (highest for zoledronate), route of administration, cumulative dose, duration of treatment and if applicable, type of malignant disease.[13]
- Osteonecrosis of the external auditory canal after bisphosphonate treatment has been described very rarely in case reports.[6] Most cases were associated with long term bisphosphonate use for two years or longer and had possible risk factors including: steroid use, chemotherapy, ear infection or operation or cotton bud use.[14]

- Atypical femoral fractures occur rarely in patients receiving bisphosphonates and are considered a class effect of bisphosphonates.[15] Risk factors include Asian race, femoral bowing and glucocorticoid use. A systematic search of the literature revealed that the absolute risk was consistently low, ranging between 3.2-50 cases/100,000 person-years of exposure. This estimate appeared to double with prolonged duration of bisphosphonate use (more than three years, median duration seven years), and declined with discontinuation.[6] As the optimum duration of bisphosphonate treatment for osteoporosis has not been established, the need for continued treatment should be re-evaluated particularly after five or more years of use.[15]
- In a cohort study from Denmark, use of alendronate in excess of ten years was associated with a 30% lower risk of hip fracture and no increase in the risk of fractures of the subtrochanteric femur and femoral shaft, supporting an acceptable risk benefit balance in terms of fracture outcomes.[6]
- Discontinuation of bisphosphonate therapy is advised in patients who develop an atypical fracture, weight-bearing activity should be restricted, adequate calcium and vitamin D should be ensured, and alternative treatment options considered where appropriate. Surgical treatment with intramedullary nailing is often recommended.[6]

A potential **disadvantage** of bisphosphonate treatment breaks is that while some patients may benefit from a bisphosphonate free period as their therapeutic effects last for some time after pausing therapy, there is limited evidence to support this. Recommendations on duration are based on limited extension studies in postmenopausal women.[11] A primary care Spanish study published in 2023, including 3,680 postmenopausal women suggested that deprescribing bisphosphonates in women at higher risk who have already received five years of treatment did not increase fracture risk. Women at lower risk, who continued the treatment, showed a higher incidence of fracture compared to women deprescribed treatment.[16]

Refer to PrescQIPP bulletin 231: Bisphosphonate treatment for osteoporosis

Antidepressants

Antidepressants have a role in the therapeutic management of depression and anxiety when used appropriately in line with NICE guidance. However, effective, personalised care should include regular reviews of whether the treatment is working, the depression or anxiety has resolved or if the harms may now outweigh the benefits.[17,18]

- Discuss stopping antidepressants through shared decision making with a person who has depression taking into account: benefits, risk of relapse, history of depression, side effects, harms of the antidepressant outweighing the benefits, the patient wanting to stop taking the medication, risk of withdrawal effects or previous difficulties the patient has experienced with withdrawing and psychological and psychosocial interventions.
- Treatment may need to be taken for at least six months after the remission of symptoms, but should be reviewed regularly.
- Review treatment for people continuing with antidepressant medication to prevent relapse at least every six months.
- Be aware of the harmful effects and withdrawal symptoms on stopping antidepressants which affect well-being and personal, occupational and social functioning. In practice this means reducing the dose at a pace that is tolerable for the patient, which for some patients can mean tapering for several months or longer. These effects and symptoms could last many months.[17-19]

Advantages and disadvantages of antidepressant treatment breaks

There may be variability between different antidepressant groups or individual medicines within the same group. Some **advantages** of treatment breaks are to evaluate:

- Effectiveness, resolution of symptoms or lack of benefit
- If harms outweigh he benefits

- If the patient wants to stop taking the medication
- Side effects.[2,17-19]

A disadvantage of antidepressant treatment breaks is that they may cause withdrawal symptoms which require dose tapering when treatment breaks are undertaken. Withdrawal symptoms are common and include insomnia, increased anxiety, and flu-like symptoms. Although withdrawal symptoms often resolve within one to two weeks, they can persist for weeks to months and care should be taken to distinguish between withdrawal symptoms and relapse of the underlying condition the antidepressants were used to treat. The incidence of withdrawal symptoms can be reduced by tapering doses gradually over a period of weeks. In practice, this means reducing the dose at a pace that is tolerable for the patient, which for some patients can mean tapering for several months or longer. However, there is limited evidence as to which dose-reduction schedules work best.[2,18]

For further information refer to the PrescQIPP antidepressant deprescribing algorithm, PrescQIPP bulletin 330: Antidepressants and the Maudsley deprescribing guidelines.

ADHD stimulant medication

Trials of treatment-free periods (or dose reductions) should be considered where appropriate in adults, children and young people prescribed ADHD stimulant medication.[20] The evidence indicates that withdrawal from pharmacological treatment for ADHD is associated with consistent reductions in side effects of treatment.[1] A planned break in treatment may allow 'catch up' growth. However, limited evidence suggests that withdrawal may lead to a worsening in ADHD symptoms.[20] The NICE guideline [NG87] evidence review, withdrawal from pharmacological treatment and drug holidays, conclusions and evidence for withdrawal from treatment and drug holidays is tabulated in table 2.[1]

Table 2: NICE [NG87] conclusions on drug withdrawal and drug holidays for ADHD pharmacological treatments[1]

Evaluation	Committee conclusion
Evaluating the effect of withdrawing pharmacological treatment in people who have experienced a positive response to a trial of pharmacological treatment	• Withdrawal from pharmacological treatment was associated with a risk in the exacerbation of symptoms of ADHD. • However, the committee noted that a number of children, young people and adults in the studies continued to experience an improvement in symptoms following withdrawal, usually while taking a placebo. • In children and young people, the committee noted, based on their experience, that withdrawal may also be associated with an increased risk of deterioration in behaviour; however there was little evidence that withdrawal had a significant impact on quality of life and behaviour in adults. • The committee considered that this may reflect a greater need for pharmacological treatment in children and young people compared to adults, who may have developed improved coping strategies over time. • The committee noted that withdrawal from pharmacological treatment was associated with consistent reductions in side effects of treatment.
Evaluating the effect of a structured drug holiday	• The committee noted that the only evidence found was for weekend breaks from medication use and not for any longer periods of drug holiday and only for methylphenidate. • The committee came to a consensus decision that it is likely to be very patient specific as to whether a patient may benefit from a break from treatment. Tying in with the discontinuations review, it was recommended that it should be a clinician's decision whether a patient may benefit from a short trial of discontinuation.

Advantages and disadvantages of ADHD treatment breaks

Many people already take treatment breaks from their ADHD medication at weekends or certain days. In addition, the national shortage of ADHD medication may result in an opportunity to go onto a treatment break.[21]

Some **advantages** of a treatment break include:

- Easing of medication side effects such as lack of appetite, growth delay, weight loss, sleep troubles, or stomach pain.[21]
  - For growth delay (in children and young people where they have not met the height expected for their age as per centiles), NICE [NG87] on ADHD: diagnosis and management, specifically recommends to consider a planned break in treatment (in conjunction with dietary input) over school holidays to allow 'catch-up' growth.[21]
- An opportunity to evaluate if other therapies (such as support in educational setting/work, practical advice around managing ADHD symptoms and or talking therapies) are effective.[21]
- Evaluation of ADHD symptoms; if ADHD symptoms (especially hyperactivity) lessen or resolve over time.[21]
- Evaluation of severity of ADHD symptoms when not taking medication.[21]

Potential disadvantages of a treatment break include:

- Re-emergence or worsening of ADHD symptoms; hyperactivity, impulsivity, and inattention may become problematic again within a day or so of stopping medication.
- Increased need to be attentive, e.g. attention during difficult tasks like driving.
- Increased risk of impulsive behaviours, e.g. being indulgent, underestimating tasks, or acting without thinking.
- There may be a delay in symptoms resolving after re-commencing ADHD medication.[21]

For further information refer to PrescQIPP bulletin 302: Prescribing in ADHD

Chronic pain management

Chronic pain (also known as persistent or long term pain)[22] is complex with challenges for assessment and long term management.[23] Opioids and gabapentinoids may be beneficial for acute and end of life pain but there is little evidence that they are helpful for long term pain (lasting over three months).[24] Individual responses to analgesia vary considerably, both in terms of efficacy and side-effects; even with the same chronic pain syndrome, the underlying pain mechanisms may differ between individuals.[11] Effective, personalised care should include shared decision making with patients and incorporate:

- At least regular annual reviews with review frequency increased if there are any changes to medication, underlying pain syndrome or comorbidities.[11]
- Review people on opioids who are at high risk of opioid side effects, with frailty or on high dose opioids. High dose opioids are defined as:
  - Above 120mg/day oral morphine equivalent. The risk of harm increases substantially at doses above an oral morphine equivalent of 120mg/day, but there is no increased benefit: tapering or stopping high dose opioids needs careful planning and collaboration.[24]
  - In Scotland, >50mg/day oral morphine equivalent (for people on doses >90mg/day oral morphine equivalent pain specialist advice or review should be sought.)[23]
- Re-evaluate benefit and lack of adequate benefit; if a patient has pain that remains severe despite opioid treatment it means it is not working and should be stopped or tapered, even if no other treatment is available. With complex pain, patients may have refractory and disabling symptoms, particularly if they are on high opioid doses.[24]

- Evaluation and review of underlying pain syndrome or co-morbidities; a very detailed assessment of the many emotional influences on their pain experience is essential[24] along with involvement of the specialist pain management team.
- Evaluation of harm, tolerance and withdrawal effects.

Advantages and disadvantages of treatment breaks for chronic pain management

Some **advantages** of a treatment break include to:

- Review response; there is little evidence that opioids or gabapentinoids are helpful for long term pain.[24]
- Reduce presence or risk of side effects of medicines used for chronic pain for example: falls, dizziness, orthostatic hypotension, itch, dry mouth, miosis, urinary retention, nausea, vomiting, dyspepsia, constipation, respiratory depression, headaches, cognitive impairment (e.g. confusion), drowsiness, over-sedation, impaired concentration (e.g. increased risk of car accidents), mood changes or dependence.[11]
- Reduce dependence and tolerance.
- Reduce inappropriate treatment for current indication.
- Reduce drug interactions.
- Reduce drug-disease interaction.
- Reduce high drug burden index.
- Evaluate adherence.
- Patient preference.

Some potential **disadvantages** of treatment breaks for pain management include:

- That there is limited information on dose tapering. However, a US review found that patients participating in intensive pain management interventions that incorporated opioid tapering may experience improvements in pain severity and pain-related function and that patients who taper opioids with less intensive co-interventions may have unchanged pain severity and pain-related function.[25]
- Patient reluctance.
- Patient engagement required.
- Potential for withdrawal effects.
- Patients' insight into own beliefs of pain perception.

For further information please refer to:

- PrescQIPP bulletin 353: Dependence forming medications September 2024.
- PrescQIPP bulletin 284: Chronic Pain January 2022.

Non-steroidal anti-inflammatory drugs (NSAIDs)

To maximise patient safety, the lowest effective dose of NSAID should be used over the shortest period of time to control symptoms.[11] The NICE guideline on chronic (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain [NG193] does not recommend the use of NSAIDs in chronic primary pain. The evidence suggested that short-term use of NSAIDs made no difference to people's quality of life, pain or psychological distress. A small amount of evidence suggested that NSAIDs reduced physical function, compared with placebo.[22] NSAID use can be associated with a range of serious side effects including cardiovascular events, gastrointestinal complications, renal failure and hypersensitivity reactions.[11] In view of the risks of harm with NSAIDs (gastrointestinal bleeding) and the lack of evidence of short term or long term effectiveness, the NICE committee decided to recommend against starting NSAIDs for chronic primary pain.[22]

This provides an opportunity to introduce a treatment break and consider alternatives, such as a topical NSAID, or physiotherapy or a different analgesic such as paracetamol.[26]

The following apply in implementing an NSAID treatment break:

- Prescribe the lowest effective NSAID dose, for the shortest possible time, and review the need for continued use at each consultation.
- Prioritise older patients, patients with increased cardiovascular risk, patients with type 2 diabetes, and patients with reduced renal function or a history of renal problems.
- Review any NSAIDs that are not recommended as first line treatment: Naproxen (up to 1000 mg per day) or ibuprofen (up to 1200 mg per day) are the recommended first-line choices for adults based on our current knowledge of NSAIDs and cardiovascular risk; ibuprofen is the most appropriate NSAID for children.[27]
- Avoid prescribing long-acting formulations of NSAIDs, where possible, as these are associated with an increased risk of gastrointestinal side effects.[26]

Advantages and disadvantages of NSAID treatment breaks

Advantages of NSAID treatment breaks would be to reduce the risk of adverse events and inappropriate use, such as:

- Cardiovascular disease: risk of thrombotic events, (e.g. myocardial infarction and stroke) independent of baseline cardiovascular risk factors or duration of NSAID use. However, the greatest risk may be in those receiving high doses long term.
- Serious gastro-intestinal toxicity: the risk is higher in the elderly and those with a history of peptic ulcer disease or gastrointestinal bleeding, unless taken with concurrent PPI or H2-receptor antagonist.
- In elderly patients the use of NSAIDs is potentially inappropriate (STOPP criteria). If prescribed, NSAIDs can cause:
  - Increased risk of gastro-intestinal bleeding with concurrent use of a vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitor, and corticosteroid therapy or anti-platelet therapy without PPI prophylaxis.
  - Risk of deterioration in renal function in patients with an eGFR less than 50 mL/minute/1.73 m^2.[11,26]

A potential disadvantage of an NSAID treatment break includes a relapse of symptoms. However, alternative therapy such as a topical NSAID, physiotherapy or paracetamol could be trialled depending on the severity of symptoms.[26]

For further information refer to PrescQIPP bulletin: 265 Non-steroidal anti-inflammatory drugs (NSAIDs)

Topical corticosteroid use

Eczema flare-ups require short bursts of treatments with topical corticosteroids, usually for time periods of seven to 14 days to bring a flare up under control.

It is also important to consider having a break from the use of a topical corticosteroid. There is no agreed-upon length of time for this; a steroid treatment break of at least two weeks may be recommended, or four weeks might be advised after using potent or very potent topical steroids.

People with more severe eczema who experience very frequent flares are sometimes advised to use topical steroids as 'weekend therapy'. Weekend therapy is when topical steroids are applied on two consecutive days a week to the areas where the eczema usually flares, for several months at a time. This can help prevent the almost continuous flare cycle, meaning that in the long-run, less topical steroid is needed to control the eczema than if each flare were treated as it occurred.[28,29]

Advantages and disadvantages of topical corticosteroid treatment breaks

Some **advantages** of topical corticosteroid treatment breaks are to reduce the risk of long term side effects and withdrawal effects. However, withdrawal effects can also be a disadvantage of a topical corticosteroid treatment break. Withdrawal reactions are thought to occur after long term continuous or inappropriate use of topical corticosteroids (particularly those of moderate to high potency). Signs and symptoms are reported to happen within days to weeks of stopping long term topical corticosteroid treatment. A flare of the underlying skin disorder is the most common withdrawal reaction. Rarely, a specific type of withdrawal reaction may occur in which skin redness extends beyond the initial area of treatment, with burning or stinging that is worse than the original condition.[30]

The National Eczema Society provide patient information on getting on top of eczema flare-ups which may be of use.

For further information on topical corticosteroid withdrawal reactions

Refer to PrescQIPP bulletin 307: Cost effective prescribing in dermatology

Medication for insomnia and anxiety

Benzodiazepines and Z-drugs should only be used for periods of two to four weeks. Hypnotics should not be prescribed indiscriminately and routine prescribing is undesirable.[11] The long term use of benzodiazepines and Z-drugs for insomnia and anxiety are of limited benefit and have well documented harms including tolerance, dependence, risk of falls and cognitive impairment. Best practice is to prescribe the lowest effective dose for the shortest time (up to two to four weeks) and use only after non-drug measures are found to be ineffective. If long term treatment is taken, discuss with the person the benefits and risks of continuing the current dose, adjusting the dose or stopping the medicine and enquire about their willingness to withdraw from the drug.[31,32]

The following points apply when prescribing and considering implementing a treatment break:

- Non-pharmacological treatments including sleep hygiene and psychological approaches should be continued alongside prescribing and if prescribing of medication stops.[31,32]
- Before prescribing a benzodiazepine or Z-drugs, explain the risks and have an agreed plan with the individual about how to stop treatment.
- Benzodiazepines are indicated for the short-term treatment of anxiety that is severe, disabling, or causing the patient unacceptable distress, occurring alone or in association with insomnia or short-term psychosomatic, organic, or psychotic illness.[11] Z-drugs are licensed for the short-term management of insomnia[31]; benzodiazepines should be used only when the insomnia is severe, disabling or causing the patient extreme distress.[11]
- Modified-release melatonin 2mg once daily for insomnia, for an adult aged 55 years and over, can be taken for up to 13 weeks.
- Daridorexant treatment length should be as short as possible. The need for continued treatment should be assessed within three months of starting and periodically thereafter.[11] Part of the three month assessment could include a discussion with the patient on taking a treatment break.

Also refer to:

- PrescQIPP bulletin 353: Dependence forming medications September 2024.
- PrescQIPP bulletin 352: Insomnia September 2024.

Advantages and disadvantages of medication for insomnia and anxiety treatment breaks

Some **advantages** of insomnia and anxiety treatment breaks are to reduce the risk of tolerance, dependence, risk of falls and cognitive impairment.[31,32]

Potential **disadvantages** of treatment breaks include:

- Withdrawal symptoms, (e.g. insomnia, anxiety, irritability, gastrointestinal symptoms) often occur, especially once doses have been reduced to approximately 25 percent of the original dose.[2]
- Strategies to help with withdrawal effects include:
- If such symptoms appear, patients should be reassured that they are usually mild and subside in days to several weeks.[2]
- Maintain the current dose for one to two weeks and then resume the taper.[2]
- For patients who have previously failed attempts at treatment breaks, understanding reasons for failure, (e.g. overly rapid tapering) can be used to formulate new discontinuation plans with greater likelihood of success and provide reassurance. With proper intervention and support, up to 60 to 80 percent of benzodiazepine users have been able to stop using these medications.[2]

Proton pump inhibitors (PPIs) (excluding Barrett's oesophagus)

PPIs should only be prescribed when needed for a recognised indication and for an minimum appropriate duration at the lowest effective dose, taking into account the person's preference and clinical circumstances.[11,33]

Offer people on long term treatment an annual or regular review of their symptoms and treatment to determine whether long term treatment is still indicated.[11,33]

Prioritise treatment breaks:

- In patients who have been taking a PPI for a minimum of four weeks and have had a complete resolution of their symptoms.
- Where the risks outweigh the benefits.
- Where ongoing use is not indicated, e.g. prescribing for ulcer prophylaxis and NSAID has been stopped.

Implement treatment breaks, encouraging the person to:

- Step down or stop treatment, if possible and appropriate.
- Ensure there is no co-morbidity or co-medication that requires long term acid suppression therapy:[34]
  - » Use a PPI or H2 receptor antagonists at at the lowest effective dose (or as needed) to control symptoms.
  - » Consider self-treatment with antacid and/or alginate therapy, although this is not recommended for long term or continuous use.
  - » Remind patients about lifestyle strategies.[34]

Advantages and disadvantages of PPI treatment breaks

Advantages of PPI treatment breaks include reduction in side effects such as:

- Long term PPI treatment may be associated with uncommon, serious side effects such as:
  - » Hypomagnesaemia — symptoms include muscle twitching, tremors, vomiting, fatigue, and loss of appetite. There are case reports after one year of PPI therapy, but it may occur after three months. This usually improves after magnesium replacement therapy and discontinuation of the PPI. Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia.
  - » Increased risk of fractures — especially when used at high doses for over a year in the elderly.
  - » Clostridium difficile infection — due to the effect of decreasing gastric acidity.[34]
- Rare or very rare side effects including:
  - » Subacute cutaneous lupus erythematosus (SCLE), which can occur weeks, months, or years after exposure to a PPI. If suspected, discontinue the PPI and seek specialist advice if needed.

- Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) have been reported very rarely, and rarely with omeprazole treatment.[34]

Potential disadvantages of treatment breaks

Stopping treatment may cause rebound acid hypersecretion syndrome. This may occur after stopping long term PPI therapy, although this may be more a theoretical risk than clinical phenomenon.[34] Gradual reduction may be more effective than abrupt discontinuation and this should be supported with lifestyle modifications.[35]

Refer to PrescQIPP bulletin 267: Proton Pump Inhibitors (PPIs): Long term safety and gastroprotection.

Antimuscarinics in urinary incontinence

Regular reviews of overactive bladder (OAB) medication are recommended in NICE [NG123] Urinary incontinence and pelvic organ prolapse in women: management published in April 2019. This helps to determine if treatment is working, the symptoms have resolved or harms outweigh benefits.[36]

Recommendations include to:

- Offer a review in primary care to women who remain on long term medicine for overactive bladder or urinary incontinence every 12 months, or every six months if they are aged over 75.[36]
- Advise use of bladder diaries.[36]
- Review men taking anticholinergics for lower urinary tract symptoms every four to six weeks until symptoms are stable, and then every six-12 months.[37]
- Offer a treatment break through shared decision making for example for a maximum of four weeks after six months of treatment to reassess effectiveness or side effects.

Advantages and disadvantages of treatment breaks of antimuscarinics used in urinary incontinence

Advantages include to assess effectiveness, side effects and to minimise risks as appropriate. It is important to be aware of anticholinergic burden; current medications affecting the total antimuscarinic load and increased evidence that the effects are associated with an increased risk of cognitive impairment, falls and all-cause mortality in older people. The potential for harm increases with age and frailty. When undertaking review of treatment, stop medicines if there is no absolute need or switch to a medicine with a lower anticholinergic burden score.[38] For further information on anticholinergic burden refer to the PrescQIPP bulletin anticholinergic burden.

Potential **disadvantages** of a treatment break include relapse of symptoms, however alternative treatment options such as lifestyle interventions (reduction in caffeine/fluid intake and losing weight if BMI greater than 30), pelvic floor muscle training and bladder training can be evaluated.[36]

How to initiate a treatment break

- Identify drugs (antidepressants, bisphosphonates, proton pump inhibitors, hypnotics, medication for attention deficit hyperactivity disorder (ADHD), chronic pain management and urinary incontinence) or conditions that may be suitable for a treatment break. There are PrescQIPP GP clinical system searches available within the dependence forming medicines resources which can be used to identify patients on antidepressants, hypnotics and chronic pain management. The PrescQIPP bisphosphonate treatment for osteoporosis GP clinical system searches can be used to identify patients prescribed a bisphosphonate. The PrescQIPP PPIs - Long term safety and gastroprotection GP clinical systems searches can be used to identify patients prescribed long term PPIs.

- Encourage a systematic and proactive approach:
  - Select a therapeutic area
  - Undertake an audit to identify suitable patients
  - Invite patients for medication review – refer to flowchart (page 15)
  - Communicate with the patients offering a shared care personalised approach explaining why they are being offered a treatment break, advantages, disadvantages, monitoring and other interventions that can be adopted, e.g. lifestyle, duration of treatment break and how to deal with relapse and concerns.[2]

Refer to PrescQIPP deprescribing algorithms

Other areas to consider for a treatment break

Also consider high-risk patient characteristics for a treatment break from certain medication to improve patient safety. There may be an overlap or progression with/to deprescribing. This group includes:

- Polypharmacy
- Multimorbidity
- Renal impairment
- Medication nonadherence
- Limited life expectancy, frailty and dementia, palliative care – changing goals
- Older age – reducing risk of falls/improving cognitive function, reducing anticholinergic burden
- Patients who wish to take a treatment break due to side effects, beliefs or inconvenience.

Refer to PrescQIPP webkit Polypharmacy and deprescribing

Overcoming barriers when introducing treatment breaks

Issues to consider to overcome potential barriers to having a treatment break include:

- Improve communication between clinicians and devolving of responsibility.[2]
- Improve clinical inertia (continuation along a path of treatment without re-evaluation or staying with the "status quo"). Starting a medication is familiar and considered a positive action, (i.e. doing something to help the patient), while treatment breaks are less familiar and may be considered a lower priority or as withdrawing care.[2]
- Be aware of current evidence for a treatment break: there may be a relative lack of evidence and guidelines to inform treatment breaks (compared with initiation of medications). This, coupled with uncertainly over whether the medication is beneficial to the individual, can mean that there is limited objective impetus to implement a treatment break.[2]
- Review patient and/or family reluctance with effective communication and discussion. Shared decision making is key.[2,39]
- Ensure appropriate consultation time is given for a medication review.[2]
- Ensure there is a process to avoid unintended restart of medication if a patient requests it. The pharmacy may also continue to automatically request that medication or dispense it if requested by the patient. To avoid this, it can be helpful to directly contact the patient's pharmacy by telephone to ensure that the medication is discontinued.[2]
- Be aware and address challenges in recognising potential for treatment breaks. This may be addressed through:
  - Use of electronic prescribing support and audit and feedback services where available to enable proactive breaks.

- Realignment of expectations of benefits and harms of medication use (both patients and clinicians tend to overestimate the benefits of medication use and underestimate the harms).
- Considering adverse drug reactions in the differential diagnosis of new symptoms or a change in condition.
- Attending treatment break continuing education opportunities.
- Discussing treatment break cases.
- Inclusion of treatment break recommendations in clinical practice guidelines.[2]

Addressing patient's concerns about treatment breaks (also see shared decision making)

It is important to explore reluctance, emotions, fears and how treatment breaks will take place making sure that what matters to the person is truly taken into account. Strategies include:

- Explain the lack of evidence for the benefits of continuing a medicine (particularly among older adults with polypharmacy and multimorbidity) along with the lack of evidence.[2]
- Consider the benefits and harms of continuation against the benefits and harms of discontinuation.[2]
- If the patient has concerns, request the patient to ask the specialist, for example "next time you see your cardiologist, make sure to tell them about this symptom you are having, and ask if it's safe to stop this medication."[2]

Figure 1 on the next page is a flow chart which aims to help explain a treatment break to a patient. This can be locally adapted.

Figure 1. How to explain a treatment break to a patient

Clear communication tailored to the individual or carers

- Ask the person what is important to them when considering a treatment break.
- Allocate time for medication review to discuss a treatment break
- Discuss information about aims of the treatment break, benefits, side effects, preferences, patient and/or family reluctance, expectations, fears and emotions
- Discuss treatment goals for a treatment break – are they objective or subjective?
- Explain why and how treatment breaks will take place
- Use patient information leaflets (attachment 1)

Shared Decision Making

Has this information been understood? e.g. in between each chunk of information use methods such as teach back to check understanding before moving on.

Why are they being offered a treatment break?

- Discuss the benefits of a treatment break, e.g. lack of potential benefits of the medication in line with guidance, risk of harm or lack of evidence on long term use
- Discuss potential of reduction in side effects with treatment break
- Explain that it is a trial and opportunity to review if the medication is still providing a benefit
- Discussion on how the treatment break will take place i.e. will the medicine be stopped or tapered

What are the benefits/advantages?

- Reduction of medication related harm
- Reduced side effects or reduced risk of side effects (resulting in hospitalisation or mortality)
- Improved quality of life
- Reduction in tolerance
- Reduction in medication burden

What are the disadvantages?

- Return of symptoms
- Increased monitoring requirements
- Disease flare or activity
- Change in patient's condition
- Withdrawal effects
- Unintentionally restarted

What monitoring will take place?

- Monitor symptoms and/or worsening or return of condition. Use questionnaires or assess objectively
- Explain what to do if the patient notices a change and safety net the patient appropriately (e.g. what symptoms to be aware of, time period and who to contact)
- Advise of follow-up appointment (telephone or face–to-face) for monitoring
- Frequency of monitoring should be clear (electronic text messaging, in person or a combination of these)
- Explain the reason for taper if this is applicable
- Offer alternative strategies to control symptoms

How long will the treatment break last?

Explain the duration and method of recall

Communicate clearly with other clinicians involved in care through consultation notes

How to deal with impact of treatment break and concerns

- Consider if starting at a lower dose may be an option after the treatment break
- Document the plan after the treatment break (e.g. if there is an option to restart medication at a lower dose or if there is an option for treatment breaks to be re-attempted)

Document treatment break – e.g. Bisphosphonate prophylaxis suspended SNOMED code: 700110004; Discontinued repeat medication SNOMED code: 711621000000109 Recall, e.g. use medication review date, Ardens template – recall date, text message

Shared decision making

Determine the patient's preferences for involvement in the decision-making process.[2]

- Discuss patient goals, preferences and elicit the patient's experiences with their medications in order to identify medications suitable for treatment breaks. Understanding their attitudes toward treatment breaks and tailoring these recommendations to "what matters" for the patient provides a patient-centred approach.[2]
- Discuss the "why" (why should the medicine be stopped?) and "how" (how will the withdrawal and monitoring be done?)[2]
- Discussion of the risk of side effects as a rationale for treatment breaks is generally preferred by older adults.[40,41] Combining a discussion of the risk of side effects or potential for harm with rationale about a lack of benefit may optimise patient acceptance of treatment breaks. Explain the treatment break as a temporary cessation in therapy (including tapering), with reassurance that the medication(s) will be restarted as appropriate.[2]
- Explain treatment breaks as optimising care. Discuss what alternative strategies are being taken to manage the symptom or disease the deprescribed medication was intended to treat.[2]
- Elicit and address concerns and fears about treatment breaks as patients may be reluctant to stop a medication if they think it is still necessary and may be concerned about being told to stop a medicine that for years they were urged to take or was described as "lifelong treatment." Other concerns may include fear of their condition returning, fear of a withdrawal reaction, or a nonspecific fear of change.[2,40,41]
- If the patient has concerns about medication withdrawal, the reasons for this should be explored (e.g. fear or belief the medication is necessary). If they are well-informed about the likely risks and benefits and place a greater value on the potential benefit than the likely harm of continuation, then breaks may not be appropriate (unless there is a clear and present risk of harm). However, the conversation can be revisited at regular intervals, particularly when there are changes in the patient's condition or there is new evidence.[2]
- Ensure clear documentation throughout.
- The use of patient information leaflets (PILs) may aid in communication and shared decision-making around treatment breaks.[2] Provide a patient information leaflet – attachment 1.

How frequently should you monitor someone on a treatment break?

Undertake a baseline check when a treatment break is considered, frequency of monitoring will vary according to the medication and patient. It is important that people know to contact the GP surgery if they have any problems during their treatment break. Refer to attachment 2 for template text messages.

Ensuring that patients are not lost to follow up at the end of a treatment break

- Provide a recall message for ensuring that patients are reviewed at the end of their treatment break. Add a reminder in the notes.
- Inform the patient to make an appointment for a review at the end of their treatment break and ensure they are given the date to contact the surgery.
- Use GP practice system recalls, text messages and SNOMED CT codes.

Useful resources

- The Polypharmacy and Deprescribing Webkit provides resources to support deprescribing through the bulletin, flow chart, high risk medication review.

- Refer to PrescQIPP IMPACT Improving Medicines and Polypharmacy Appropriateness Clinical Tool to consider treatment duration, response, side effects and patient preferences, with recommendations and considerations for appropriately continuing or stopping medicines.
- The All Wales Medicines Strategy Group Polypharmacy in older people
- PrescQIPP Deprescribing algorithms
- PrescQIPP bulletin 330. Antidepressants
- PrescQIPP bulletin 284. Chronic pain
- PrescQIPP bulletin 336. Reducing Opioid prescribing in chronic pain
- PrescQIPP bulletin 231. Bisphosphonate treatment for osteoporosis
- PrescQIPP bulletin 353. Dependence forming medicines
- To support implementation of the NICE guideline on shared decision making, Keele University and NICE have worked in partnership to develop an online learning package. This is suitable for all healthcare professionals and aims to equip people with the skills and knowledge they need to have good-quality shared decision-making conversations with the people they are caring for. The learning package is free to access. It takes approximately four hours to complete and is made up of six modules:
  - Orientation and background
  - Cognitive psychology: the science of how we all make decisions
  - Evidence-based medicine
  - Probability and uncertainty
  - Consultation skills
  - Practising shared decision making, staying up to date

Costs and savings

Data relates to England, Wales, Northern Ireland, Isle of Man and Scotland NHSBSA (Jun–Aug24) and Public Health Scotland (Jun-Aug24).

It is difficult to quantify the benefits for patients arising from undertaking treatment breaks, for example a reduction in side effects, improved growth during ADHD medication treatment breaks. Adverse drug reactions are responsible for 16.5% of all hospital admissions.[42] Any reduction in side effects which avoid hospital admissions will be of immense benefit to the patient and be cost saving also.

£1.3 billion is spent annually on the prescribing of medicines which may be suitable for treatment breaks in England, Wales, Northern Ireland, Isle of Man and Scotland (table 3).

Table 3. Spend on medicines suitable for treatment breaks in England, Wales, Northern Ireland, Isle of Man and Scotland (NHSBSA Jun-Aug2024, and Public Health Scotland Jun-Aug2024)

Country	Latest 12 month spend
England	£1,073,917,717
Wales	£71,292,511
Northern Ireland	£58,505,799
Isle of Man	£3,242,833
Scotland	£179,154,614
Total	£1,386,113,474

If patients were reviewed and the medication stopped for a treatment break and this resulted in a 1% reduction in spend, **this would lead to savings of £13.9million in England, Wales, Northern Ireland, Isle of Man and Scotland. This equates to £18,497 per 100,000 patients.**

Table 4 provides the breakdown in annual savings by country for a 1% reduction in costs arising from treatment breaks.

Table 4: 12 months cost avoidance by country for treatment breaks (NHSBSA Jun-Aug2024 and Public Health Scotland Jun-Aug24)

12 month cost avoidance	England	Wales	Northern Ireland	Isle of Man	Scotland
ADHD	£1,221,109	£39,215	£50,570	£948	£146,259
Antidepressants	£2,161,929	£162,526	£123,205	£2,882	£369,206
Bisphosphonates	£87,769	£5,210	£3,415	£147	£18,187
Chronic pain management	£3,329,812	£246,998	£206,024	£7,031	£551,695
Hypnotics	£297,200	£24,573	£41,581	£901	£77,331
NSAIDs	£338,199	£28,305	£21,046	£663	£104,016
PPIs	£1,578,935	£89,767	£78,585	£2,817	£276,602
Topical corticosteroids	£687,515	£42,888	£28,492	£962	£117,098
Urinary incontinence	£1,036,709	£73,444	£32,139	£1,305	£131,152
Totals	**£10,739,177**	**£712,925**	**£585,058**	**£17,655**	**£1,791,546**

The PrescQIPP scorecards incorporate a wide range of indicators such as:

- ADHD cost per 1,000 patients.
- High dose opioid items per 1,000 patients.
- Benzodiazepines (caps & tabs) items per benzodiazepine caps & tabs (BNF 4.1 sub-set) COST based STAR PU.
- Melatonin cost per 1,000 patients.
- PPIs items per proton pump inhibitors (BNF1.3.5) cost based STAR PU.
- Drugs for urinary incontinence (BNF 7.4.2) cost per 1,000 cost based ASTRO PUs.

These scorecard indicators allow organisations to see where they are outliers or have significant opportunity. Once organisations select the indicators to implement, the scorecards allow for monitoring progress against the targets set. The scorecard data allows NHS organisations to review the estimated cost savings from implementing medicine optimisation projects and achieving the same prescribing as

either the top 10% or 25% (depending on which value is selected) of organisations for that measure. The data can be filtered at ICB/HB, PCN, place and practice level. The PrescQIPP scorecards 12 months savings data supports prioritisation of medicine optimisation initiatives and monitoring progress against objectives. These priorities can also be viewed in the PrescQIPP practice planning report and practice visit and progress reports. These reports can be saved as pdfs and downloaded by practices or emailed to them.

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Additional PrescQIPP resources

Including implementation tools and data:	https://www.prescqipp.info/our-resources/bulletins/bulletin-358-treatment-breaks/

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