Pharmaceutical Society of Australia

Biologic (b/tsDMARD) dispensing and counselling checklist

Dispensing	Yes	No	N/A
Have you confirmed: The indication for biological (b/tsDMARD) therapy? ***Note: This question is relevant to both bDMARDs and tsDMARDs.*** Please tick the relevant indication:* *Inflammatory Arthritis* ☐ *Rheumatoid arthritis* ☐ *Psoriatic arthritis* ☐ *Ankylosing spondylitis* *Inflammatory Bowel Disease* ☐ *Crohn disease* ☐ *Ulcerative colitis* *Psoriasis* ☐ *Plaque psoriasis* **Indications not listed are outside the scope of this checklist*	☐	☐	☐
Have you confirmed: Current medical conditions and medicines, and assessed appropriateness of biological therapy?# Considerations include (but not limited to): • thromboembolic disease (with JAK inhibitors) • pregnancy and/or breastfeeding (for female patients of child-bearing age) • active infection • allergies • other medicines (including complementary, herbal) and foods, for review of potential interactions *Please refer to relevant references/resources for a complete list of precautions/contraindications for consideration including SHPA bDMARDs Quick Reference Guide, Australian Medicines Handbook, Therapeutic Guidelines, Australian Immunisation Handbook.* ***Note: This question is relevant to both bDMARDs and tsDMARDs*** # *Record any changes in your dispensing system and My Health Record.*	☐	☐	☐
Did you check whether the patient's condition is well- controlled?	☐	☐	☐
Did you check if the patient is biologic naive or if this is ongoing therapy?	☐	☐	☐
For ongoing therapy, did you confirm which brand the patient has been using?	☐	☐	☐
Did you check whether their dose has remained the same, been increased or reduced?	☐	☐	☐
If dose was either increased or reduced, did you clarify the reason(s) for the dose adjustments?	☐	☐	☐
Note: These questions are relevant to both bDMARDs and tsDMARDs			

Dispensing (continued)	Yes	No	N/A
If switching to a different brand/biosimilar, have you:			
• Explained to the patient what biosimilars are	☐	☐	☐
• Explained that biosimilars must have a demonstrable similarity in efficacy and safety to the reference biologic and must have been assessed by the TGA	☐	☐	☐
• Used positive framing in your discussion to highlight the benefits of substitution	☐	☐	☐
• Confirmed the "brand substitution not permitted" box on the prescription is not ticked	☐	☐	☐
• Discussed with the patient about biosimilar substitution including change in device (provided the patient has agreed to the change)	☐	☐	☐
• Reviewed the patient's medicines history to confirm brand substitution is appropriate to avoid inadvertent and multiple switching	☐	☐	☐
• Confirmed that the patient has agreed to the switch	☐	☐	☐
• Discussed biologic substitution with the prescriber	☐	☐	☐
Note: This question is relevant to bDMARDs only			
Did you record the brand and batch number of the b/tsDMARD dispensed in the dispensing system and My Health Record? ***Note: This question is relevant to both bDMARDs and tsDMARDs***	☐	☐	☐

Counselling	Yes	No	N/A
Have you informed the patient of the active ingredient and brand dispensed? ***Note: This question is relevant to both bDMARDs and tsDMARDs***	☐	☐	☐
Have you encouraged the patient to be familiar with their preferred brand, to avoid inadvertent switches between brands (provide a medicines list if needed e.g. NPS Medicines List)? ***Note: This question is relevant to bDMARDs only***	☐	☐	☐
Have you explained how to correctly self-administer their bDMARD injection medicine with instructions specific to the device dispensed? *Useful patient resources/information include (but not limited to): available patient support programs, clinicians/nurses* ***Note: This question is relevant to bDMARDs only (tsDMARDs are oral tablets)***	☐ ☐	☐ ☐	☐ ☐
Have you discussed storage requirements for the medicine? ***Note: This question is relevant to both bDMARDs and tsDMARDs***	☐	☐	☐
Have you discussed how to dispose of the bDMARD injection device and provided a sharps container if needed? ***Note: This question is relevant to only bDMARDs (tsDMARDs are oral tablets)***	☐	☐	☐
Have you described the more common adverse effects of the medicine and how these can be managed? Considerations include (but not limited to): • Immunosuppression/infection and the instructions re: witholding *Please refer to relevant references/resources for a complete list of precautions/contraindications for consideration including SHPA bDMARDS Quick Reference Guide, Australian Medicines Handbook, Therapeutic Guidelines, Australian Immunisation Handbook.* ***Note: This question is relevant to bDMARDs and tsDMARDs***	☐	☐	☐
Have you explained the dosage for the medicine, including: ○ Frequency of dosing and what to do if a dose is missed (***both bDMARDs and tsDMARDs***) ○ Importance of adherence and strategies to remember when doses are due (***both bDMARDs and tsDMARDs***) ○ Multiple injections may be required to achieve the dose prescribed (***bDMARDs only, as tsDMARDs are oral tablets***)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐

Counselling (continued)	Yes	No	N/A
Have you informed the patient that live vaccines (e.g. *Zostervax* for adult non-travelling population) should be avoided during biological therapy, however influenza, pneumococcal and COVID vaccinations are safe to have? *Please refer to relevant references/resources for a complete list of relevant/applicable live vaccines for consideration including SHPA bDMARDs Quick Reference Guide, Australian Medicines Handbook, Therapeutic Guidelines, Australian Immunisation Handbook.* ***Note: This question is relevant to both bDMARDs and tsDMARDs***	☐	☐	☐
Have you provided the patient written information specific to the biologic dispensed (e.g. device information)? ***Note: This question is relevant to both bDMARDs and tsDMARDs***	☐	☐	☐

Suggested patient action plan - pharmacists to discuss with patients on a biologic *(applies to both bDMARDs and tsDMARDs, unless otherwise indicated)*	Yes	No	N/A
Have you discussed the following with the patient?			
• Take a photograph of the medicine dispensed to recall their preferred brand and current batch number.	☐	☐	☐
• Take care of their medicines supply and prescriptions as they can be difficult to replace.	☐	☐	☐
• Avoid accidental brand switching (***bDMARDs only***) and treatment delays (***both bDMARDs and tsDMARDs***) by calling ahead to their pharmacy to ensure their preferred brand is in stock.	☐	☐	☐
• Attend medical reviews and blood tests as requested to enable monitoring of treatment.	☐	☐	☐
• Ensure they have an appointment to obtain a new prescription from their specialist, when they have one repeat prescription remaining.	☐	☐	☐
• Report new or worsening medical conditions or new medicines to their doctor.	☐	☐	☐
• Report any side effects to their pharmacist or doctor.	☐	☐	☐
• Seek medical advice if they have signs of infection such as fever, chills, loss of appetite or lethargy.	☐	☐	☐

This document has been developed in collaboration with

+TARGETED THERAPIES ALLIANCE

Helping consumers and health professionals make safe and wise therapeutic decisions about biological disease-modifying antirheumatic drugs (bDMARDs) and other specialised medicines. Funded by the Australian Government Department of Health through the Value in Prescribing bDMARDs Program Grant.

The Alliance is led by NPS MedicineWise and includes Arthritis Australia, Australia and New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network, Australian Rheumatology Association, Cochrane Musculoskeletal, Council of Australian Therapeutic Advisory Groups, Pharmaceutical Society of Australia, Quality Use of Medicines and Pharmacy Research Centre (University of South Australia) and Society of Hospital Pharmacists of Australia.

shpa

CATAG
Council of Australian Therapeutic Advisory Groups

NPS MEDICINEWISE

Purpose of this checklist

This checklist has been designed to support pharmacists in the dispensing and counselling of biologics for the following indications*:

- Inflammatory arthritis
  - Rheumatoid arthritis
  - Psoriatic arthritis
  - Ankylosing spondylitis
- Inflammatory bowel disease
  - Crohn disease
  - Ulcerative colitis
- Plaque psoriasis

* Indications not listed are outside the scope of this checklist

How to use this checklist

This checklist has been divided into three sections:

- dispensing checklist
- counselling checklist
- suggested patient action plan

The use of biologics and biosimilars is a rapidly changing area and this checklist should not be used as the sole source of information about these medicines.

Use of this counselling checklist presumes all necessary clinical checks/assessments (e.g. contraindications/drug-interactions etc) have been conducted. If clinical checks have not been conducted, consider referring to resources including (but not limited to) *Australian Medicines Handbook, Therapeutic Guidelines, SHPA Quick Reference Guide*.

This checklist only refers to the following biologics for the following conditions

bDMARDs	*tsDMARDs*	*Conditions*
Abatacept (IV) Reference product (brand): Orencia IV Abatacept (subcut) Reference product (brand): Orencia SC Adalimumab Reference product (brand): Humira Certolizumab pegol Reference product (brand): Cimzia Etanercept Reference product (brand): Enbrel Golimumab Reference product (brand): Simponi Guselkumab Reference product (brand): Tremfya Infliximab IV Reference product (brand): Remicade Infliximab SC Reference product (brand): Remicade (subcutaneous Remicade is not available in Australia) Ixekizumab Reference product (brand): Taltz Risankizumab Reference product (brand): Skyrizi Rituximab Reference product (brand): Mabthera (no longer PBS listed) Secukinumab Reference product (brand): Cosentyx Tildrakizumab Reference product (brand): Ilumya Tocilizumab (IV) Reference product (brand): Actemra IV Tocilizumab (subcut) Reference product (brand): Actemra SC Ustekinumab (IV) Reference product (brand): Stelara IV Ustekinumab (subcut) Reference product (brand): Stelara SC Vedolizumab (IV) Reference product (brand): Entyvio IV Vedolizumab (subcut) Reference product (brand): Entyvio SC	Baricitinib Reference product (brand): Olumiant Tofacitinib Reference product (brand): Xeljanz Upadacitinib Reference product (brand): Rinvoq	Inflammatory arthritis • Rheumatoid arthritis • Psoriatic arthritis • Ankylosing spondylitis Inflammatory bowel disease • Crohn disease • Ulcerative colitis Psoriasis • Plaque psoriasis

Patient resources

- NPS MedicineWise. Understanding biological medicines, their biosimilars and the PBS - Understanding biosimilars: For your patients https://www.nps.org.au/consumers/understanding-biosimilars
- Biosimilar medicines the basics for consumers and carers; Biosimilar medicines: the basics https://www1.health.gov.au/internet/main/publishing.nsf/content/biosimilar-awareness-initiative/$File/Biosimilar-medicines-the-basics-for-consumers-and-carers-Bochure.pdf
- Biosimilar Hub. Information on biosimilars for consumers and carers - Consumer/carer brochure (available in multiple languages): https://biosimilarhub.com.au/consumer/consumer-carer-brochure/
- Australian Rheumatology Association https://rheumatology.org.au
- Arthritis Australia https://arthritisaustralia.com.au
- Crohn's and Colitis Australia https://www.crohnsandcolitis.com.au

Pharmacist resources

- Australian Medicines Handbook
- Therapeutic Guidelines
- The Australian Immunisation Handbook
- PSA's Practice Audit Tool - MTX and bDMARDs: Optimising use in rheumatoid arthritis https://my.psa.org.au/s/training-plan
- SHPA's bDMARDs Quick Reference Guide https://bdmards.shpa.org.au/

References

Australian Injectable Drugs Handbook, 8th Edition. Society of Hospital Pharmacists, 2021. Last updated 26/7/21. Accessed 30/7/21.

Australian Medicines Handbook (AMH). Australian Medicines Handbook Pty Ltd, 2021. Last updated July 2021. Accessed 30/7/21.

Australian Rheumatology Association. Australian clinician guide for the use of immunomodulatory drugs in autoimmune rheumatic diseases at the time of COVID-19 vaccination. https://rheumatology.org.au/For-Healthcare-Professionals/Clinical-Resources/COVID-Information ANZMUSC. An Australian Living Guideline for the Pharmacological management of Inflammatory Arthritis. 2020 [version 0.3]. Available from: https://mskguidelines.org

Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au. https://immunisationhandbook.health.gov.au/vaccination-for-special-risk-groups/vaccination-for-people-who-are-immunocompromised

Gastroenterological Society of Australia (GESA) website: https://www.gesa.org.au

Gastroenterological Society of Australia (GESA). COVID-19 vaccination in patients with gastrointestinal and liver disorders. Update 21 June 2021. https://www.gesa.org.au/index.cfm//education/covid-19/ Van Langenberg D, Ward M (eds). Clinical Update for General practitioners and Physicians: Inflammatory Bowel Disease. Gastroenterological Society of Australia. 2018. https://www.gesa.org.au/public/13/files/Education%20%26%20Resources/Clinical%20Practice%20Resources/IBD/2018_IBD_Clinical_Update_May_update.pdf

Product Information. Accessed via Australian Register of Therapeutic Goods. https://www.tga.gov.au/australian-register-therapeutic-goods

SHPA bDMARDS Quick Reference Guide. https://bdmards.shpa.org.au/monographs/

The Australasian College of Dermatologists https://www.dermcoll.edu.au/about/position-statements/

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