Dalbavancin

Adult outpatient parenteral antimicrobial therapy (OPAT) good practice prescribing guide

Dalbavancin is a lipoglycopeptide with bactericidal activity against Gram-positive bacteria only. It is licensed for acute bacterial skin and skin structure infections.

This guide shares practical experience of the use of dalbavancin in an OPAT setting. We took an evidence based approach to create the guidance. We also used expert consensus and practical experience from across NHS Scotland.

This drug summary does not provide specific treatment guidance. Individual patient treatment should take into account the core principles of antimicrobial stewardship. This includes selection of the appropriate antimicrobial for the shortest duration with oral therapy being preferred, whenever possible. Please also refer to the British National Formulary (BNF) or Summary of Product Characteristics (SPC). These have more information on licensed use, drug interactions and use in pregnancy and breast feeding. When using unlicensed medicines, doses or indications, follow local health board governance processes.

It is strongly recommended that OPAT services in Scotland adhere to the Key performance indicators for the management of patients in an outpatient parenteral antimicrobial therapy (OPAT) setting.

Dalbavancin

Contents

1 Indication and dose

Licensed indication(s) in the OPAT setting	Dose
Acute bacterial skin and skin structure infections	Day 1; 1000mg one-off dose and review on Day 8 for consideration of oral therapy or further 500mg one-off dose **OR** Day 1; 1500mg one-off dose (equivalent to a 2 week course of treatment)

Off-label indications

It is recommend that off-label use is agreed with local OPAT infection specialist.
Scottish experience of use in practice for off-label indications are below.

Off-label indications in the OPAT setting	Dose
Uncomplicated *Staphylococcus aureus* bacteraemia (no deep source of infection identified or suspected and clinically well)	• If suitable for OPAT and it is 7 days or less since last positive blood culture; 1500mg one-off dose • If suitable for OPAT and it is more than 7 days since last positive blood culture; 1000mg one-off dose
Bone and joint infection (eg first stage revision of joint)	1500mg dosed on Day 1 and repeated on Day 8 Equivalent duration 4-6 weeks
Bone and joint infection (eg debridement and implant retention)	1000mg one-off dose on Day 1 then 500mg on Day 8 and weekly thereafter Duration dependent upon source of infection and availability of oral antibiotic options
Infective Endocarditis (Native and Prosthetic valves)	1000mg one-off dose on Day 1 then 500mg on Day 8 and weekly thereafter Duration usually to complete 6 weeks total effective therapy

Complicated skin and soft tissue infections (cSSTI)
SAPG has developed an OPAT pathway for the management of adults with complicated skin and soft tissue infections (cSSTI)

This pathway supports reduced hospital admissions and promotes early discharge for patients with complicated skin and soft tissue infections.

2 Route and method of administration

Refer to Summary of Product Characteristics (SPC) or Medusa for further information.
Each vial must be reconstituted and the total dose further diluted prior to administration. See information below:

Reconstitution

- Reconstitute each 500mg vial with 25ml water for injection
- Further dilute total dose to give a final concentration of 1-5mg/L (eg add 500-1000mg to 250ml and add 1500mg to 500ml Glucose 5 *%)*
  Note: adding 75ml of reconstituted vials to 250ml of diluents would give final concentration of 4.62mg/L
- For patients who are diabetic use 500ml Glucose 5% with caution

Method of administration

- Administer as an IV infusion over 30 minutes
- Flush IV line before and after with 5% glucose solution for infusion

3 Dose adjustments and monitoring

3.1 Dose adjustments

Renal impairment

Licensed indication; 'Acute bacterial skin and skin structure infections'

Renal function Creatinine Clearance (CrCl)	**Dose adjustment**
30 – 79 ml/min	No dose adjustment necessary
< 30 ml/min **OR** Irregular haemodialysis	Day 1; 1000mg single dose (equivalent to a 2 week course of treatment) **OR** Day 1; 750 mg single dose and review on Day 8 for consideration of oral therapy or further 375 mg single dose
Regular thrice weekly haemodialysis (eg Mon/Wed/Fri)	No dose adjustment necessary

Unlicensed indications

Discuss all patients with pharmacy

Information on dosing and efficacy in CrCl less than 30 ml/min is limited especially for unlicensed or off-label indications.

The following dose suggestions are unlicensed.

Consider reducing all doses as follows:
- if 500mg is indicated give 375mg
- if 1000mg is indicated give 750mg
- if 1500mg is indicated give 1000mg

Other dosage adjustments

Patient characteristic	Dosage advice
Hepatic impairment	No dose adjustment necessary
Obesity	No dose adjustment necessary
Underweight	BMI calculation BMI = weight in kg/ (height in m)^2 Information on dosing and possible toxicity in patients with low body weight (BMI less than 15 mg/kg^2 or weight less than 40 kg) is limited especially for unlicensed or off-label indications. The following dose suggestions are unlicensed: • Discuss all patients with pharmacy • Consider reducing all doses as follows: - if 500mg is indicated give 375mg - if 1000mg is indicated give 750mg - if 1500mg is indicated give 1000mg

3.2 Monitoring requirements

Frequency	Recommended monitoring
Baseline	Urea and Electrolytes, LFTs, CRP and FBC
Weekly monitoring (*Note* this may be more frequent if clinically necessary)	Urea and Electrolytes, LFTs, CRP and FBC Consider waiting for results before redosing
Therapeutic drug monitoring	No therapeutic drug monitoring required
Follow up	Ensure follow up is arranged with referring specialty or with an infection specialist

4 Contraindications, cautions and adverse effects

4.1 Contraindications

History of severe hypersensitivity (eg anaphylactic reaction) to dalbavancin and any other type of glycopeptide including vancomycin and teicoplanin or excipients.

4.2 Cautions

- Information on dosing and efficacy in CrCl less than 30 ml/min is limited
- Information on and possible toxicity in patients with low body weight (BMI less than 15 mg/kg^2 or weight less than 40 kg) is limited

4.3 Adverse effects

Please note that this is not an exhaustive list. Refer to the BNF or SPC

Infusion related
rapid intravenous infusion can cause flushing of upper body, urticaria, pruritus or rash. Stopping or slowing the infusion may results in cessation of these reactions.
Common
headache nausea diarrhoea
Uncommon
anaemia, thrombocytosis, eosinophilia, leucopenia, neutropenia flushing decreased appetite insomnia raised liver function tests raised lactate
Unknown frequency
bronchospasm

5 Interactions

Please note that this is not an exhaustive list. Refer to the BNF or SPC

Interaction	Details
Warfarin	Must ensure follow up with local anticoagulant service for INR monitoring and any necessary dosage adjustments. Patients should also be counselled on signs of over anticoagulation (eg bruising, bleeding).
Hormonal contraception	Additional precautions are no longer necessary when dalbavancin (a non-enzyme inducing drug) is taken with combined or progestogen-only contraceptive preparation, unless diarrhoea or vomiting occurs. See manufacturer's guidance.
Food interactions	No known serious interactions with food.

For the use of other antibiotics in an OPAT setting please refer to the SAPG website

Table of abbreviations

ASAP	Association of Scottish Antimicrobial Pharmacists
BMI	Body mass index
BNF	British National Formulary
CrCl	Creatinine clearance
CRP	C-reactive protein
cSSTI	Complicated skin and soft tissue infections
FBC	Full blood count
LFTs	Liver function tests
OPAT	Outpatient parenteral antimicrobial therapy
SAPG	Scottish Antimicrobial Prescribing Group
SPC	Summary of Product Characteristics

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This resource has been created by the Scottish Antimicrobial Prescribing Group (SAPG) Outpatient Antimicrobial Therapy (OPAT) subgroup and The Association of Scottish Antimicrobial Pharmacists (ASAP) to support prescribing in an OPAT setting in NHS Scotland.