NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Parenteral Antimicrobial Therapy, Adult Outpatient (OPAT) Good Practice Guide

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

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

February 2023

Volume I

Ceftriaxone
Daptomycin
Dalbavancin

Created by: Scottish Antimicrobial Prescribing Group (SAPG) | Approved: Feb 2023 | Review date: Feb 2026

Scottish Antimicrobial Prescribing Group
Safeguarding antibiotics for Scotland,
now and for the future

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.

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www.sapg.scot

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1 Introduction

This aim of this good practice prescribing guide is to share practical experience in the use of antimicrobials in an OPAT setting. The information provided is not exhaustive, and recommendations are based on an evidence review, expert consensus and practical experience from NHS Scotland OPAT services.

Reference should be made to the British National Formulary (BNF) or Summary of Product Characteristics (SPC) for further licensed information, use in pregnancy and breast feeding, and for a definitive guide to drug interactions.

The drug summaries do not constitute specific treatment guidelines. Patient treatment selection should be made on an individual basis taking 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. It is strongly recommended that OPAT services adhere to the British Society of Antimicrobial Chemotherapy's updated good practice recommendations for OPAT in adults and children in the UK and the Scottish Antimicrobial Prescribing Group's (SAPG) Key performance indicators for the management of patients in an outpatient parenteral antimicrobial therapy (OPAT) setting. This current guidance supports SAPG's OPAT pathway for the management of adults with complicated skin and soft tissue infections (cSSTI) affecting their upper or lower limb(s) or face (erysipelas). Further guidance will be developed to support the use of other antimicrobials in the OPAT setting.

Where references are made to unlicensed medicines or the use of licensed medicines for off-label indications or off-label doses, it is essential to follow local health board governance processes, including approval via the antimicrobial management team and drugs and therapeutics committee.

2 Ceftriaxone

Ceftriaxone is a cephalosporin antibacterial that is licensed for many different indications including respiratory tract infections, intra-abdominal infections, complicated urinary tract infections, complicated skin and soft tissue infections, bone and joint infections and central nervous system infections.

2.1 Indication and dose

Licensed indication(s) in the OPAT setting	Dose
Intra-abdominal infections Complicated urinary tract infections (including pyelonephritis)	2g 24 hourly
Lower respiratory tract Infection Complicated skin and soft tissue infections Infections of bones and joints (except *Staphylococcus aureus* infection) Lyme Disease (except Central Nervous System) Bacterial endocarditis (sensitive Streptococcal species)	2g 24 hourly
Bacterial meningitis Central Nervous System Lyme disease Deep seated *Staphylococcus aureus* infection including bacteraemia bone and joint infections and endocarditis	4g 24 hourly **OR** 2g 12 hourly

Complicated skin and soft tissue infections (cSSTI)
SAPG has developed an OPAT pathway for the management of adults with cSTTI affecting their upper or lower limb(s) or face (erysipelas). This will support reduced hospital admissions and promote early discharge for patients with cSSTI.

Click to access SAPG cSSTI pathway.

Ceftriaxone is recommended as first line therapy in the OPAT cSSTI pathway

2.2 Route and method of administration

Refer to Summary of Product Characteristics (SPC) or Medusa for further information

Intravenous (IV) administration

Reconstitution
Reconstitute 2g vial in 40ml sodium chloride (NaCl) 0.9%.

Method of administration

Dose	Route and method of administration
2g may be given by:	• IV injection over 5 minutes • IV infusion over 30 minutes
4g may be given by IV infusion over 60 minutes by:	• administering 2 x 2g infusions back-to-back (one after the other) • adding the total dose to an infusion bag
4g daily may be given in 2 divided doses	• 2g IV injection over 5 minutes administered twice daily • twice daily dosing may be self administered by patient at home

Can also administer via elastomeric infusion device if available **(see local/manufacturer guidance).**

Intramuscular injection (reconstitution and method of administration)

Consider intramuscular administration when the intravenous route is not possible or less appropriate for the patient

Reconstitution

Dissolve 1g ceftriaxone in 3.5ml of 1% Lidocaine Injection British Pharmacopoeia (BP). Administer the solution by deep intramuscular injection

Method of administration

- 2g dose administered as 1g injected intramuscularly into each buttock
- Inject intramuscular injections well within the bulk of a relatively large muscle and not more than 1g should be injected at one site

2.3 Dose adjustments and monitoring

2.3.1 Dose adjustments

Patient characteristic	Dosage advice
Renal impairment	Creatinine clearance (CrCl) ≤ 10 ml/min dosage should not exceed 2g daily
Hepatic impairment	No dose adjustment necessary
Obesity	No dose adjustment necessary

2.3.2 Monitoring requirements

Frequency	Recommended monitoring
Baseline	Urea and Electrolytes, liver function tests (LFTs), C-reactive protein (CRP) and full blood count (FBC)
Weekly monitoring (*Note* this may be more frequent if clinically necessary)	Urea and Electrolytes, LFTs, CRP and FBC
Therapeutic drug monitoring	No therapeutic drug monitoring required

Follow up	Ensure follow up arranged with referring specialty and/or completed with an infection specialist

2.4 Contraindications, cautions and adverse effects

2.4.1 Contraindications

History of severe hypersensitivity (eg anaphylactic reaction) to ceftriaxone and any other type of beta-lactam antibacterial agent (penicillins, monobactams and carbapenems) or excipients.

2.4.2 Cautions

- Recent history (last 8 weeks) or at high risk of *Clostridium difficile* infection.
- History of hypercalciuria; history of kidney stones.
- Patients on a controlled sodium diet. Each 1g vial of ceftriaxone contains 3.6 mmol sodium.

2.4.3 Adverse effects

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

Common
diarrhoea rash deranged lfts neutropenia, leucopenia, eosinophilia
Uncommon
nausea, vomiting headache, dizziness anaemia, coagulation disorder pruritis
Rare
bronchospasm encephalopathy urticaria
Unknown Frequency
antibiotic associated colitis haemolytic anaemia pancreatitis seizure nephrolithiasis severe skin disorders –toxic epidermal necrolysis (TEN), Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome, erythema multiforme

2.5 Interactions

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

Interaction	Details
Ceftriaxone and calcium-containing intravenous solution	**Ceftriaxone and calcium-containing solutions must not be mixed or administered simultaneously.** Diluents containing calcium (eg Ringer's solution or Hartmann's solution), should not be used to reconstitute ceftriaxone vials or to further dilute a reconstituted vial for intravenous administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when ceftriaxone is mixed with calcium-containing solutions in the same intravenous administration line. Calcium-containing solutions can be given sequentially, via different lines or the same line if flushed well and giving sets changed in between.
Warfarin	Must ensure follow up with local anticoagulant service for international normalised ratio (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 ceftriaxone (non-enzyme inducing drug) is taken with any combined or progestogen-only contraceptive preparation unless diarrhoea or vomiting occurs. See manufacturer guidance
Food interactions	No known serious interactions with food.

3 Daptomycin

Daptomycin is a cyclic lipopeptide with activity against Gram-positive bacterial only. It is licensed for complicated skin and soft tissue infections (cSSTI), right sided infective endocarditis as a result of *Staphylococcus aureus* and *Staphylococcus aureus* bacteraemia.

3.1 Indication and dose

Licensed indications

Licensed indication(s) in the OPAT setting	Dose
Complicated skin and soft tissue infection (cSSTI) without *Staphylococcus aureus* bacteraemia	Licensed dose is 4mg/kg but in practise some centres use off-label 6mg/kg (see cSSTI pathway below)
cSSTI with *Staphylococcus aureus* bacteraemia	6mg/kg 24 hourly
Right sided endocarditis	Licensed dose is 6mg/kg but in practise higher doses are frequently used (see off-label indications below)

Off-label Indications

Off-label indications in the OPAT setting	Dose
Bone and joint infection **OR** Bacteraemia (excluding Enterococcal organisms)	8-10 mg/kg* 24 hourly
Right or left sided native/prosthetic valve or device related infective endocarditis **OR** Bacteraemia involving Enterococcal organisms	10-12 mg/kg* 24 hourly

*Use total body weight total body weight (TBW) or adjusted body weight (AdjBW) if body mass index (BMI) ≥ 30 kg/m^2. (*See also obesity section below*)

Complicated skin and soft tissue infections (cSSTI)

SAPG has developed an OPAT pathway for the management of adults with cSSTI affecting their upper or lower limb(s) or face (erysipelas). This will support reduced hospital admissions and promote early discharge for patients with cSSTI.

Click to access SAPG cSSTI pathway

Daptomycin is used as an alternative to ceftriaxone if patient has severe anaphylaxis or other life-threatening penicillin or beta-lactam allergy or *C. difficile* concern (including episode in previous 3 months).

Suggested dosing guidance in (cSSTI)

Recommended dose of daptomycin IV is 4-6mg/kg and review daily

The following dosing advice for SSTIs in the table below is an example of pragmatic dosing in practise based on a 6mg/kg (actual body weight) dosing regimen. It is for guidance only and may be locally adapted or modified.

Doses have been rounded up to the nearest 350mg or 500mg vials.

Table: Daptomycin SSTI 6mg/kg dosing regimen adapted from Greater Glasgow and Clyde OPAT

Body weight	6mg/kg dosing*
<59kg	350mg
59-83kg	500mg
84-117kg	700mg
118-142kg	850mg
>142kg	discuss with pharmacy

*Dose rounded to nearest vial

3.2 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 may be further diluted prior to administration as follows:

Reconstitution

Reconstitute 350mg vial with 7ml and 500mg with 10ml NaCl 0.9 %

Method of administration

Total dose may be administered via:

- Slow IV injection over minimum 2 minutes. No further dilution needed
- IV infusion over 30 minutes. Further dilute up to 50ml NaCl 0.9 %

Daptomycin has a low pH and may cause venous irritation and tissue damage in cases of extravasation

Rounding of doses

- Where possible use whole vials (350mg and 500mg vial strengths are available).
- If the total calculated dose is ≤ 10% above the available whole vial round the dose down (eg calculated dose 530mg, prescribe 500mg).
- Dose rounding may result in a higher mg/kg dose than recommended above. Doses > 12mg/kg are not recommended. Discuss with pharmacy if the dose is unclear.

3.3 Dose adjustments and monitoring

3.3.1 Dose adjustments

Renal impairment

As renal function may fluctuate it is important to monitor renal function at least weekly and adjust dosing interval if required during the treatment course.

Information on optimal dosing and efficacy in CrCl <30 ml/min is limited. The following dose suggestions are unlicensed.

Note: Calculate the mg/kg dose using total body weight (TBW) or AdjBW if BMI ≥ 30 kg/m^2 (see also obesity section below).

Renal function (Creatinine clearance (CrCl))	Dose adjustment
< 30 ml/min **OR** if patient is receiving irregular or daily haemodialysis	Reduce frequency to 48 hourly and more frequent monitoring is required (see below for monitoring requirements)
Regular three times weekly haemodialysis (eg Mon/Wed/Fri)	Give on haemodialysis days only (after haemodialysis)

Other dosage adjustments

Patient characteristic	Dosage advice
Hepatic impairment	No dose adjustment necessary
Obesity	If BMI ≥ 30 kg/m^2 use the patient's **adjusted body weight** (AdjBW) to calculate the daptomycin mg/kg dose: **BMI is calculated using the following equation:** BMI = Weight (kg)/ (Height (m))^2 If the patient's BMI is over 30 use **AdjBW equation** to calculate weight for daptomycin dosing. **AdjBW equation** AdjBW = (0.4 x (TBW – Ideal body weight (IBW))) + IBW **IBW is calculated using the following equation:** IBW = ((Ht (cm) – 152.4cm)/ 2.54) * 2.3 + 50kg (male) or 45.5kg (female)

3.3.2 Monitoring requirements

Frequency	Recommended monitoring
Baseline	Urea and Electrolytes, LFTs, CRP and FBC, creatine phosphokinase (CPK)
Weekly monitoring (*Note* this may be more frequent if clinically necessary)	Urea and Electrolytes, LFTs, CRP, FBC, CPK (2-3 times weekly if poor renal function or receiving renal replacement therapy) For patients on higher doses consider more frequent monitoring **Monitoring advice for patients that should be discussed at weekly appointment**

	Patients should be advised to report muscle pain Monitor for breathlessness or new cough as this may indicate eosinophilic pneumonitis (*Note* not usually associated with peripheral blood eosinophilia)
Therapeutic drug monitoring	Routine daptomycin therapeutic drug monitoring is not recommended because there is no clear evidence that links daptomycin concentration monitoring with clinical outcome. However, daptomycin trough concentrations may be useful in patients requiring renal replacement therapy to predict toxicity CPK should be measured at least weekly as a useful and easily measured surrogate marker of potential toxicity. More frequent monitoring may be required in renal impairment or those at risk of developing myopathy eg patients on statins. Please consider the following pragmatic approach. Daptomycin should be discontinued if: • Symptomatic rise in CPK observed (especially if CPK > 5 times upper normal limit) • Asymptomatic rise in CPK observed (CPK > 10 times upper limit normal)

Haemodialysis

The following table gives therapeutic drug monitoring guidance for patients on three time's weekly haemodialysis

Haemodialysis dosing regimen	Target trough concentration
Regular three times weekly haemodialysis (eg Mon/Wed/Fri)	Take a daptomycin 72 hour trough level (long dialysis interval) Recommended daptomycin trough concentration is 5-20mg/L (10 – 20mg/L in severe sepsis) Seek advice from pharmacy if the reported trough concentration is out with this recommended target concentration range Daptomycin samples are sent to North Bristol Antimicrobial Reference Laboratory for analysis; therefore, these may take 3-5 working days to be reported

Follow up

Ensure follow up arranged with referring specialty or an infection specialist

3.4 Contraindications, cautions and adverse effects

3.4.1 Contraindications

History of severe hypersensitivity (eg anaphylactic reaction) to daptomycin or excipients.

3.4.2 Cautions

- Daptomycin may interact with recombinant thromboplastin reagents leading to falsely elevated INR test results. Most haematology departments use RecombiPlasTin 2G reagent, which is not known to be affected by daptomycin. Please check with your haematology department and if any concerns use a capillary INR test, which is not known to interfere.
- Higher daptomycin plasma concentrations and total exposure may be observed in patients with preexisting chronic renal impairment, which may increase risk of myopathies.
- Most brands of daptomycin vials must be kept in the fridge but please check storage instructions on individual vials as there is at least one brand on the market that requires room temperature storage. Please refer to guidance provided by the manufacturer regarding disruption of the cold chain.

3.4.3 Adverse effects

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

Common
gastrointestinal disturbance abnormal liver function tests
Uncommon
myopathy and rhabdomyolysis Advise patient to report any new muscle symptoms. Where possible, the drug's manufacturers recommend avoiding concomitant administration with other drugs, which may also be associated with myopathies, eg simvastatin, sodium fusidate, etc. However, there is Scottish experience of continuing these drug combinations with patient counselling and weekly measurement of CPK levels to monitor for any potential toxicity.
Rare but serious
eosinophilic pneumonitis Advise patients of this potential side effect and monitor for new onset respiratory symptoms (fever, cough, dyspnoea and hypoxia) or new infiltrates on chest x-ray. Peripheral eosinophil count may be normal or raised. If this reaction is suspected, stop daptomycin and discuss with an infection specialist immediately.
Unknown frequency
peripheral neuropathy severe cutaneous adverse reaction

3.5 Interactions

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

Interaction	Details
Statins	Where possible the manufacturers of daptomycin recommend avoiding concomitant administration with any other drug, which may enhance the risk of myopathies and rhabomyolysis. However, marketing research supports the continued prescription of statins together with daptomycin. If statin continues consider twice weekly CPK monitoring.
Warfarin	Must ensure follow up with anticoagulant service (or GP as per local arrangement) 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 daptomycin (non-enzyme inducing drug) is taken with combined or progestogen-only contraceptive preparation unless diarrhoea or vomiting occurs. See manufacturer guidance.
Drug or food interactions	No known serious interactions with food.

4 Dalbavancin

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

4.1 Indication and dose

Licensed indications

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 cSSTI affecting their upper or lower limb(s) or face (erysipelas). This will support reduced hospital admissions and promote early discharge for patients with complicated skin and soft tissue infections.

Click to access SAPG cSSTI pathway

4.2 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

4.3 Dose adjustments and monitoring

4.3.1 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 <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 < 15 mg/kg^2 or < 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

4.3.2 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 arranged with referring specialty or with an infection specialist

4.4 Contraindications, cautions and adverse effects

4.4.1 Contraindications

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

4.4.2 Cautions

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

4.4.3 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

4.5 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 (non-enzyme inducing drug) is taken with combined or progestogen-only contraceptive preparation unless diarrhoea or vomiting occurs. See manufacturer guidance.
Food interactions	No known serious interactions with food

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6 Table of abbreviations

AjBW	Adjusted body weight
BMI	Body mass index
BNF	British National Formulary
CPK	Creatine phosphokinase
CRP	C-reactive protein
cSTTI	Complicated skin or soft tissue infection
DRESS	Drug rash with eosinophilia and systemic symptoms
FBC	Full blood count
IBW	Ideal body weight
INR	International normalised ratio
OPAT	Outpatient parenteral antimicrobial therapy
SAPG	Scottish Antimicrobial Prescribing Group
SHC	Stanford Health Care
SPC	Summary of Product Characteristics
SSTI	Skin or soft tissue infection
TBW	Total body weight
TEN	Toxic epidermal necrolysis