NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE Guideline Diabetic foot problems: prevention and management Draft for consultation, April 2019

This guideline covers preventing and managing foot problems in children, young people and adults with diabetes. The guideline aims to reduce variation in practice.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- People with diabetic foot problems, their families and carers

We have reviewed the evidence on antimicrobial prescribing for diabetic foot infection. You are invited to comment on the new and updated recommendations. These are marked as **[2019]**.

You are also invited to comment on recommendations that NICE proposes to delete from the 2015 guideline.

We have not reviewed the evidence for the recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification.

See <u>update information</u> for a full explanation of what is being updated.

This draft guideline contains:

- the draft recommendations
- · recommendations for research

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- rationale and impact sections that explain why the committee made the 2019 recommendations and how they might affect practice
- the guideline context.

Information about how the guideline was developed is on the <u>guideline's page</u> on the NICE website. This includes the evidence reviews, the scope, and details of the committee and any declarations of interest.

Full details of the evidence and the committee's discussion on the 2019 recommendations are in the <u>evidence reviews</u>. Evidence for the 2011 and 2015 recommendations is in the <u>full version</u> of the 2015 guideline

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1 Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>your care</u>.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

| 2 | 1.1 | Care within 24 hours of a person with diabetic foot |
|----------------------|-------|--|
| 3 | | problems being admitted to hospital, or the detection of |
| 4 | | diabetic foot problems (if the person is already in hospital) |
| 5 6 | 1.1.1 | Each hospital should have a care pathway for people with diabetic foot problems who need inpatient care. [2011] |
| 7 8 9 | 1.1.2 | A named consultant should be accountable for the overall care of the person, and for ensuring that healthcare professionals provide timely care. [2011] |
| 10 11 12 13 | 1.1.3 | Refer the person to the multidisciplinary foot care service within 24 hours of the initial examination of the persons feet. Transfer the responsibility of care to a consultant member of the multidisciplinary foot care service is a diabetic foot problem is the dominant clinical factor for inpatient care. [2011] |
| 15 16 17 | 1.1.4 | The named consultant and the healthcare professionals from the existing team should remain accountable for the care of the person unless their care is transferred to the multidisciplinary foot care service. [2011] |
| 18 | 1.2 | Care across all settings |
| 19 20 | 1.2.1 | Commissioners and service providers should ensure that the following are in place: |

| 1 | | A foot protection service for preventing diabetic foot problems, and for |
|----------|-------|---|
| 2 | | treating and managing diabetic foot problems in the community |
| 3 | | A multidisciplinary foot care service for managing diabetic foot |
| 4 | | problems in hospital and in the community that cannot be managed by |
| 5 | | the foot protection service. This may also be known as an |
| 6 | | interdisciplinary foot care service. |
| 7 | | Robust protocols and clear local pathways for the continued and |
| 8 | | integrated care of people across all settings including emergency care |
| 9 | | and general practice. The protocols should set out the relationship |
| 10 11 | | between the foot protection service and the multidisciplinary foot care service. |
| 12 | | Regular reviews of treatment and patient outcomes, in line with the |
| 13 | | National Diabetes Foot Care Audit. [2015] |
| . • | | rational Biasotos Foot Gallo Fladia [2010] |
| 14 | 1.2.2 | The foot protection service should be led by a podiatrist with specialist |
| 15 | | training in diabetic foot problems, and should have access to healthcare |
| 16 | | professionals with skills in the following areas: |
| 17 | | Diabetology. |
| 18 | | Biomechanics and orthoses. |
| 19 | | • Wound care. [2015] |
| | | |
| 20 | 1.2.3 | The multidisciplinary foot care service should be led by a named |
| 21 | | healthcare professional, and consist of specialists with skills in the |
| 22 | | following areas: |
| 23 | | Diabetology. |
| 24 | | Podiatry |
| 25 | | Diabetes specialist nursing. |
| 26 | | Vascular surgery. |
| 27 | | Microbiology. |
| 28 | | Orthopaedic surgery. |
| 29 | | Biomechanics and orthoses. |
| 30 | | Interventional radiology. |
| 31 | | • Casting. |
| | | ··· · · · · · |

| 1 | | • Wound care. [2015] |
|----------------------------|----------|--|
| 2 3 4 | 1.2.4 | The multidisciplinary foot care service should have access to rehabilitation services, plastic surgery, psychological services and nutritional services. [2015] |
| 5 6 7 8 | 1.2.5 | Healthcare professionals may need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care settings, to ensure equality of access to foot care assessments and treatments for people with diabetes. [2015] |
| 9 10 | 1.2.6 | Take into account any disabilities, including visual impairment, when planning and delivering care for people with diabetes. [2015] |
| 11 | 1.3 | Assessing the risk of developing a diabetic foot problem |
| 12 | Frequenc | cy of assessments |
| 13 14 | 1.3.1 | For children with diabetes who are under 12 years, give them, and their family members or carers (as appropriate), basic foot care advice. [2015] |
| 15 16 17 18 19 | 1.3.2 | For young people with diabetes who are 12–17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment, and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an appropriate specialist. [2015] |
| 21 22 | 1.3.3 | For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times: |
| 20 | | \A/\dots = \display \ |
| 23 24 | | When diabetes is diagnosed, and at least annually thereafter (see recommendation 1.3.11). |
| 25 | | If any foot problems arise. |
| 26 27 | | On any admission to hospital, and if there is any change in their status while they are in hospital. [2015] |

Assessing the risk of developing a diabetic foot problem

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| 2 3 4 | 1.3.4 | When examining the feet of a person with diabetes, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors: |
|--|-------|---|
| 5 6 7 8 9 10 11 12 | | Neuropathy (use a 10 g monofilament as part of a foot sensory examination). Limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). Ulceration. Callus. Infection and/or inflammation. Deformity. Gangrene. Charcot arthropathy. [2015] |
| 15 16 17 | 1.3.5 | Use ankle brachial pressure index in line with the NICE guideline on <u>lower</u> <u>limb peripheral arterial disease</u> . Interpret results carefully in people with diabetes because calcified arteries may falsely elevate results. [2015] |
| 18 19 | 1.3.6 | Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification: |
| 20 21 22 23 24 25 26 27 28 | | Low risk: no risk factors present except callus alone. Moderate risk: deformity or neuropathy or non-critical limb ischaemia. High risk: previous ulceration or previous amputation or on renal replacement therapy or |
| 30 | | neuropathy and non-critical limb ischaemia together or |

| 1 | | neuropathy in combination with callus and/or deformity or |
|----------------|----------|---|
| 2 | | non-critical limb ischaemia in combination with callus and/or |
| 3 | | deformity. |
| 4 | | Active diabetic foot problem: |
| 5 | | ulceration or |
| 6 | | spreading infection or |
| 7 | | critical limb ischaemia or |
| 8 | | - gangrene or |
| 9 | | suspicion of an acute Charcot arthropathy, or an unexplained hot, |
| 10 | | red, swollen foot with or without pain. [2015] |
| 11 | Managing | the risk of developing a diabetic foot problem |
| 12 | 1.3.7 | For people who are at low risk of developing a diabetic foot problem, |
| 13 | | continue to carry out annual foot assessments, emphasise the importance |
| 14 | | of foot care, and advise them that they could progress to moderate or high |
| 15 | | risk. [2015] |
| 16 17 | 1.3.8 | Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service. [2015] |
| 18 19 | 1.3.9 | The foot protection service should assess newly referred people as follows: |
| 20 21 22 | | Within 2-4 weeks for people who are at high risk of developing a diabetic foot problem Within 6-8 weeks for people who are at moderate risk of developing a |
| 23 | | diabetic foot problem. [2015] |
| 24 | 1.3.10 | For people at moderate or high risk of developing a diabetic foot problem, |
| 25 | | the foot protection service should: |
| 28 | | Assess the feet. Give advice about, and provide, skin and nail care of the feet. Assess the biomechanical status of the feet, including the need to |
| 27 28 29 | | · · · · · · · · · · · · · · · · · · · |

| 1 2 3 4 | | Assess the vascular status of the lower limbs. Liaise with other healthcare professionals, for example, the person's GP, about the person's diabetes management and risk of cardiovascular disease. [2015] |
|---|------------|---|
| 5 6 | 1.3.11 | Depending on the person's risk of developing a diabetic foot problem, carry out reassessments at the following intervals: |
| 7 8 9 10 11 12 13 14 15 16 | | Annually for people who are at low risk. Frequently (for example, every 3–6 months) for people who are at moderate risk. More frequently (for example, every 1–2 months) for people who are at high risk, if there is no immediate concern. Very frequently (for example, every 1–2 weeks) for people who are at high risk, if there is immediate concern. Consider more frequent reassessments for people who are at moderate or high risk, and for people who are unable to check their own feet. [2015] |
| 18 19 20 21 | 1.3.12 | People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service. [2015] |
| 22 | Patient in | formation about the risk of developing a diabetic foot problem |
| 23 24 25 26 | 1.3.13 | Provide information and clear explanations to people with diabetes and/or their family members or carers (as appropriate) when diabetes is diagnosed, during assessments, and if problems arise. Information should be oral and written, and include the following: |
| 27 28 29 30 | | Basic foot care advice and the importance of foot care. Foot emergencies and who to contact. Footwear advice. The person's current individual risk of developing a foot problem. |

| 1 | | • Information about diabetes and the importance of blood glucose control |
|---|----------|---|
| 2 | | (also see recommendation 1.3.14). [2015] |
| 3 4 5 6 7 8 9 10 | 1.3.14 | For guidance on education programmes and information about diabetes, see the <u>education and information</u> section in type 1 diabetes in adults: diagnosis and management (NICE guideline NG17), the <u>patient</u> <u>education</u> section in type 2 diabetes in adults: management (NICE guideline NG28) and the sections <u>education and information for children and young people with type 1 diabetes</u> and <u>education and information for children and young people with type 2 diabetes</u> in diabetes (type 1 and type 2) in children and young people: diagnosis and management (NICE guideline NG18). [2015] |
| 12 | 1.4 | Diabetic foot problems |
| 13 | Referral | |
| 14 15 16 17 18 19 | 1.4.1 | If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: |
| 20 21 22 23 24 25 | | Ulceration with fever or any signs of sepsis. Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). Gangrene (with or without ulceration). [2015] |
| 26272829 | 1.4.2 | For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day. [2015] |

- 2 1.4.3 Provide information and clear explanations as part of the individualised 3 treatment plan for people with a diabetic foot problem. Information should 4 be oral and written, and include the following:
 - A clear explanation of the person's foot problem.
 - Pictures of diabetic foot problems.
 - Care of the other foot and leg.
 - Foot emergencies and who to contact.
- Footwear advice.
- Wound care.

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- Information about diabetes and the importance of blood glucose control
 (also see recommendation 1.3.14). [2015]
- 13 1.4.4 If a person presents with a diabetic foot problem, take into account that
 14 they may have an undiagnosed, increased risk of cardiovascular disease
 15 that may need further investigation and treatment. For guidance on the
 16 primary prevention of cardiovascular disease, see the NICE guideline
 17 on lipid modification. [2015]

1.5 Diabetic foot ulcer

19 Investigation

- 20 1.5.1 If a person has a diabetic foot ulcer, assess and document the size, depth 21 and position of the ulcer. **[2015]**
- Use a standardised system to document the severity of the foot ulcer,
 such as the SINBAD (Site, Ischaemia, Neuropathy, Bacterial Infection,
- Area and Depth) or the University of Texas classification system. [2015]
- 25 1.5.3 Do not use the Wagner classification system to assess the severity of a diabetic foot ulcer. **[2015]**

Treatment

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28 1.5.4 Offer 1 or more of the following as standard care for treating diabetic foot ulcers:

| 1 2 3 4 5 | | Offloading. Control of foot infection. Control of ischaemia. Wound debridement. Wound dressings. [2015] |
|----------------------------|--------|---|
| 6 7 8 | 1.5.5 | Offer non-removable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers. Offer an alternative offloading device until casting can be provided. [2015] |
| 9 10 11 | 1.5.6 | In line with the NICE guideline on <u>pressure ulcers</u> , use pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing. [2015] |
| 2 3 4 5 | 1.5.7 | When treating diabetic foot ulcers, debridement in hospital should only be done by healthcare professionals from the multidisciplinary foot care service, using the technique that best matches their specialist expertise and clinical experience, the site of the diabetic foot ulcer and the person's preference. [2015] |
| 7 8 9 | 1.5.8 | When treating diabetic foot ulcers, debridement in the community should only be done by healthcare professionals with the relevant training and skills, continuing the care described in the person's treatment plan. [2015] |
| 20 21 22 | 1.5.9 | Consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service. [2015] |
| 23 24 25 26 27 | 1.5.10 | When deciding about wound dressings and offloading when treating diabetic foot ulcers, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances. [2015] |
| | | |

| 1 | 1.5.11 | Consider dermal or skin substitutes as an adjunct to standard care when |
|----|-----------|---|
| 2 | | treating diabetic foot ulcers, only when healing has not progressed and on |
| 3 | | the advice of the multidisciplinary foot care service. [2015] |
| 4 | 1.5.12 | Do not offer the following to treat diabetic foot ulcers, unless as part of a |
| 5 | | clinical trial: |
| 6 | | Electrical stimulation therapy, autologous platelet-rich plasma gel, |
| 7 | | regenerative wound matrices and dalteparin. |
| 8 | | Growth factors (granulocyte colony-stimulating factor [G-CSF], |
| 9 | | platelet-derived growth factor [PDGF], epidermal growth factor [EGF] |
| 10 | | and transforming growth factor beta [TGF-β]). |
| 11 | | Hyperbaric oxygen therapy. [2015] |
| 12 | 1.5.13 | When deciding the frequency of follow-up as part of the treatment plan, |
| 13 | | take into account the overall health of the person with diabetes, how |
| 14 | | healing has progressed, and any deterioration. [2015] |
| 15 | 1.5.14 | Ensure that the frequency of monitoring set out in the person's |
| 16 | | individualised treatment plan is maintained whether the person with |
| 17 | | diabetes is being treated in hospital or in the community. [2015] |
| 18 | 1.6 | Diabetic foot infection |
| 19 | Investiga | tion |
| 20 | 1.6.1 | If a diabetic foot infection is suspected and a wound is present, send a |
| | | |

| 20 | 1.6.1 | If a diabetic foot infection is suspected and a wound is present, send a |
|----|-------|--|
| 21 | | soft tissue or bone sample from the base of the debrided wound for |
| 22 | | microbiological examination. If this cannot be obtained, take a deep swab |
| 23 | | because it may provide useful information on the choice of antibiotic |
| 24 | | treatment. [2015] |
| | | |
| 25 | 1.6.2 | Consider an X-ray of the person's affected foot (or feet) to determine the |
| 26 | | extent of the diabetic foot problem. [2015] |
| | | |
| 27 | 1.6.3 | Think about osteomyelitis if the person with diabetes has a local infection, |
| 28 | | a deep foot wound or a chronic foot wound. [2015] |
| | | |

| 1 2 | 1.6.4 | Be aware that osteomyelitis may be present in a person with diabetes despite normal inflammatory markers, X-rays or probe-to-bone testing. |
|--------|-------------------------|--|
| 3 | | [2015] |
| 4 | 1.6.5 | If osteomyelitis is suspected in a person with diabetes but is not confirmed |
| 5 | | by initial X-ray, consider an MRI to confirm the diagnosis. [2015] |
| 6 | Treatme | nt |
| 7 | 1.6.6 | Start antibiotic treatment for suspected diabetic foot infection as soon as |
| 8 | | possible. Take samples for microbiological testing before, or as close as |
| 9 | | possible to, the start of antibiotic treatment. [2019] |
| 10 | 1.6.7 | When choosing an antibiotic for people with a suspected diabetic foot |
| 11 | | infection (see recommendations 1.6.8 and 1.6.9) take account of: |
| 12 | | • the <u>severity of diabetic foot infection</u> (mild, moderate or severe) |
| 13 | | the risk of developing complications |
| 14 | | previous microbiological results |
| 15 | previous antibiotic use | |
| 16 | | • patient preferences. [2019] |
| | To find | out why the committee made the 2019 recommendations on antibiotic |
| | treatme | nt for diabetic foot infection and how they might affect practice see |
| | rationale | e and impact. |
| | | |

Choice of antibiotic

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18 1.6.8 When prescribing antibiotics for a suspected diabetic foot infection in 19 adults aged 18 years and over, follow the recommendations in table 1. 20 [2019] 21 1.6.9 Give oral antibiotics first-line if the person can take oral medicines, and 22 the severity of their condition does not require intravenous antibiotics. 23 [2019] 24 1.6.10 Review intravenous antibiotics by 48 hours and consider switching to oral 25 antibiotics if possible. [2019]

- 1 1.6.11 Base antibiotic course length on the severity of the infection and a clinical
- 2 assessment of response to treatment. Review the need for continued
- antibiotics regularly. [2019]

4 Table 1. Antibiotics for diabetic foot infection in adults aged 18 years and over

| Mild infection - first choice oral antibiotic for 7 days (up to a further 7 days needed based on clinical assessment³; guided by microbiological results wavailable) Flucloxacillin 500 mg four times a day | | |
|--|--|--|
| needed based on clinical assessment³; guided by microbiological results wavailable) Flucloxacillin 500 mg four times a day Mild infection - alternative oral antibiotics (for penicillin allergy or if flucloxacunsuitable) for 7 days (up to a further 7 days may be needed based on clinical assessment³; guided by microbiological results when available) Clarithromycin 500 mg twice a day Erythromycin (in pregnancy) 500 mg four times a day Doxycycline 200 mg on first day, then 100 mg once a day Moderate infection - first choice antibiotics for a minimum of 7 days (up to 6 for osteomyelitis) based on clinical assessment⁴; guided by microbiological when available⁵.6.7 Flucloxacillin with or without 500 mg four times a day orally or 500 mg to 1 times a day IV Gentamicin and/or Initially 5 to 7 mg/kg once a day IV, subsequence doses adjusted according to serum gentamic concentration8 | | |
| Mild infection - alternative oral antibiotics (for penicillin allergy or if flucloxa unsuitable) for 7 days (up to a further 7 days may be needed based on clinic assessment³; guided by microbiological results when available) Clarithromycin | | |
| unsuitable) for 7 days (up to a further 7 days may be needed based on clinic assessment³; guided by microbiological results when available) Clarithromycin 500 mg twice a day Erythromycin (in pregnancy) 500 mg four times a day Doxycycline 200 mg on first day, then 100 mg once a day Moderate infection - first choice antibiotics for a minimum of 7 days (up to 6 for osteomyelitis) based on clinical assessment⁴; guided by microbiological when available⁵,6,7 Flucloxacillin with or without 500 mg four times a day orally or 500 mg to times a day IV Gentamicin and/or Initially 5 to 7 mg/kg once a day IV, subsequence doses adjusted according to serum gentamic concentration8 | | |
| Erythromycin (in pregnancy) Doxycycline 200 mg four times a day Moderate infection - first choice antibiotics for a minimum of 7 days (up to 6 for osteomyelitis) based on clinical assessment ⁴ ; guided by microbiological when available ^{5,6,7} Flucloxacillin with or without Sou mg four times a day orally or 500 mg to 1 times a day IV Gentamicin and/or Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day or 1 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV, subsequence of the substantial day IV and Initially 5 to 7 mg/kg once a day IV and I | | |
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| Moderate infection - first choice antibiotics for a minimum of 7 days (up to 6 for osteomyelitis) based on clinical assessment ⁴ ; guided by microbiological when available ^{5,6,7} Flucloxacillin with or without Solve Times a day IV Gentamicin and/or Initially 5 to 7 mg/kg once a day IV, subsequence doses adjusted according to serum gentamic concentration ⁸ | | |
| for osteomyelitis) based on clinical assessment ⁴ ; guided by microbiological when available ^{5,6,7} Flucloxacillin with or without Solve Times a day IV Gentamicin and/or Initially 5 to 7 mg/kg once a day IV, subsequence doses adjusted according to serum gentamic concentration ⁸ | | |
| times a day IV Gentamicin <i>and/or</i> Initially 5 to 7 mg/kg once a day IV, subseq doses adjusted according to serum gentam concentration ⁸ | | |
| doses adjusted according to serum gentant concentration ⁸ | | |
| | | |
| Metronidazole 400 mg three times a day orally or 500 mg times a day IV | | |
| Co-amoxiclav <i>with or without</i> 500/125 mg three times a day orally or 1.2 times a day IV | | |
| Gentamicin See doses above | | |
| Co-trimoxazole (in penicillin allergy) with or without 960 mg twice a day orally or 960 mg twice a day in severe i IV | | |
| Gentamicin and/or Initially 5 to 7 mg/kg once a day IV, subseq doses adjusted according to serum gentam concentration ⁸ | | |
| Metronidazole 400 mg three times a day orally or 500 mg times a day IV | | |
| Severe infection - first choice antibiotics for a minimum of 7 days (up to 6 weeks for osteomyelitis) based on clinical assessment ⁴ ; guided by microbiological results when available. Antibiotics given IV for at least 48 hours (until stabilised) ^{5,6,7} | | |
| As for moderate infection, but additional choices of: | | |
| Piperacillin with tazobactam 4.5 g three times a day IV (increased to 4.5 times a day if severe infection) | | |
| Ceftriaxone <i>with</i> 2 g once a day IV | | |
| Metronidazole 400 mg three times a day orally or 500 mg | | |

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| | times a day IV |
|---|--|
| Intravenous antibiotics to be added if suspected or confirmed MRSA infection (combination therapy with an intravenous antibiotic listed above) ^{6,7} | |
| Vancomycin | 15 to 20 mg/kg two or three times a day (maximum 2 g per dose), adjusted according to serumvancomycin concentration ⁹ |
| Linezolid (if vancomycin cannot be used; specialist advice only) | 600 mg twice a day |

¹ See <u>BNF</u> for appropriate use and dosing in specific populations, for example, hepatic impairment, renal impairment, pregnancy and breast-feeding, and administering intravenous antibiotics.

To find out why the committee made the 2019 recommendations on choice of antibiotic (including dose frequency, route of administration and course length) for diabetic foot infection and how they might affect practice see <u>rationale and impact</u>.

Advice

- 3 1.6.12 When prescribing antibiotics for a diabetic foot infection, give advice 4 about:
 - possible adverse effects of the antibiotic
 - seeking medical help if symptoms worsen rapidly or significantly at any time, or do not start to improve within 2 to 3 days. [2019]

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² Oral doses are for immediate-release medicines.

³ Skin takes some time to return to normal, and full resolution of symptoms at 7 days is not expected.

⁴ Review the need for continued antibiotics regularly.

⁵ Give oral antibiotics first-line if the person can take oral medicines, and the severity of their condition does not require intravenous antibiotics.

⁶ Review intravenous antibiotics by 48 hours and consider switching to oral antibiotics if possible.

⁷ Other antibiotics may be appropriate based on microbiological results and specialist advice.

⁸ Therapeutic drug monitoring and assessment of renal function is required (BNF, February 2019).

⁹ Therapeutic drug monitoring and assessment of renal function is required. A loading dose of 25 to 30 mg/kg (maximum per dose 2 g) can be used in seriously unwell people to facilitate rapid attainment of the target trough serum vancomycin concentration (BNF, February 2019).

To find out why the committee made the 2019 recommendations on advice to give people when prescribing an antibiotic for diabetic foot infection and how this might affect practice see <u>rationale and impact.</u>

1 Reassessment

- 2 1.6.13 When microbiological results are available:
- review the choice of antibiotic, and
- change the antibiotic according to results, using a narrow spectrum
 antibiotic, if appropriate. [2019]
- Reassess people with a suspected diabetic foot infection if symptoms
 worsen rapidly or significantly at any time, do not start to improve within 2
 to 3 days, or the person becomes systemically very unwell or has severe
 pain out of proportion to the infection. Take account of:
 - other possible diagnoses, such as pressure sores, gout or non-infected ulcers
 - any symptoms or signs suggesting a more serious illness or condition, such as osteomyelitis, necrotising fasciitis or sepsis
 - previous antibiotic use. [2019]

To find out why the committee made the 2019 recommendations on reassessment of people with diabetic foot infection and how they might affect practice see rationale and impact.

Prevention

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16 1.6.15 Do not offer antibiotics to prevent diabetic foot infections. Give advice 17 about seeking medical help if symptoms of a diabetic foot infection 18 develop. **[2019]**

To find out why the committee made the 2019 recommendations on antibiotics to prevent of diabetic foot infection and how they might affect practice see <u>rationale</u> and <u>impact</u>.

1.7 Charcot arthropathy

2 Investigation

1

3 1.7.1 Be aware that if a person with diabetes fractures their foot or ankle, it may 4 progress to Charcot arthropathy. [2015] 5 1.7.2 Suspect acute Charcot arthropathy if there is redness, warmth, swelling or 6 deformity (in particular, when the skin is intact), especially in the presence 7 of peripheral neuropathy or renal failure. Think about acute Charcot 8 arthropathy even when deformity is not present or pain is not reported. 9 [2015] 10 1.7.3 To confirm the diagnosis of acute Charcot arthropathy, refer the person 11 within 1 working day to the multidisciplinary foot care service for triage 12 within 1 further working day. Offer non-weight-bearing treatment until 13 definitive treatment can be started by the multidisciplinary foot care 14 service. [2015] 15 1.7.4 If acute Charcot arthropathy is suspected, arrange a weight-bearing X-ray 16 of the affected foot and ankle. Consider an MRI if the X-ray is normal but 17 Charcot arthropathy is still suspected. [2015]

18 **Treatment**

| 19 | 1.7.5 | If the multidisciplinary foot care service suspects acute Charcot |
|----|-------|---|
| 20 | | arthropathy, offer treatment with a non-removable offloading device. If a |
| 21 | | non-removable device is not advisable because of the clinical, or the |
| 22 | | person's, circumstances, consider treatment with a removable offloading |
| 23 | | device. [2015] |
| | | |
| 24 | 1.7.6 | Do not offer bisphosphonates to treat acute Charcot arthropathy, unless |
| 25 | | as part of a clinical trial. [2015] |
| | | |
| 26 | 1.7.7 | Monitor the treatment of acute Charcot arthropathy using clinical |
| 27 | | assessment. This should include measuring foot–skin temperature |
| 28 | | difference and taking serial X-rays until the acute Charcot arthropathy |
| 29 | | resolves. Acute Charcot arthropathy is likely to resolve when there is a |

| 1 | | sustained temperature difference of less than 2 degrees between both |
|---|-------|--|
| 2 | | feet and when X-ray changes show no further progression. [2015] |
| 3 | 1.7.8 | People who have a foot deformity that may be the result of a previous |
| 4 | | Charcot arthropathy are at high risk of ulceration and should be cared for |
| 5 | | by the foot protection service. [2015] |

Terms used in this guideline

7 Diabetic foot infection

- 8 Diabetic foot infection is defined by the presence of at least 2 of the following:
- local swelling or induration
- 10 erythema

6

- 11 local tenderness or pain
- 12 local warmth
- purulent discharge.

14 Severity of diabetic foot infection

- 15 Infection severity is classified as:
- Mild: local infection involving only the skin and subcutaneous tissue; if erythema,
- must be 0.5 to less than 2 cm around the ulcer (exclude other causes of
- inflammatory response, such as trauma, gout, acute Charcot neuro-
- osteoarthropathy, fracture, thrombosis and venous stasis).
- Moderate: local infection with erythema more than 2 cm around the ulcer or
- 21 involving structures deeper than skin and subcutaneous tissues (such as abscess,
- osteomyelitis, septic arthritis or fasciitis), and no systemic inflammatory response
- 23 signs.

26

- Severe: local infection with signs of systemic inflammatory response (such as
- 25 temperature >38°C or <36°C, increased heart rate or increased respiratory rate).

Recommendations for research

27 The guideline committee has made the following recommendations for research.

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1 Key recommendations for research

| 2 | 1 Intensive monitoring for people at risk of diabetic foot problems |
|--|---|
| 3 | Does intensive monitoring of people at risk of diabetic foot disease reduce the |
| 4 | morbidity associated with developing the disease and is such monitoring cost |
| 5 | effective? |
| 6 | 2 Referral criteria for the foot protection service and the multidisciplinary foot |
| 7 | care service |
| 8 | When and with what criteria should people with diabetes be referred to the foot |
| 9 | protection service or the multidisciplinary foot care service? |
| 10 | 3 Education and psycho-behavioural interventions for prevention |
| 11 | What is the role of educational models and psycho-behavioural interventions in |
| 12 | prevention of diabetic foot complications? |
| 13 | 4 Prevention strategies for Charcot arthropathy |
| 14 | What strategies may be useful in the prevention of Charcot arthropathy? |
| | |
| 15 | 5 Diabetic ulcer dressings |
| 15 16 | 5 Diabetic ulcer dressings What is the clinical effectiveness of different dressing types in treating diabetic foot |
| | |
| 16 | What is the clinical effectiveness of different dressing types in treating diabetic foot |
| 16 17 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? |
| 16 17 18 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? Other recommendations for research |
| 16 17 18 19 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? Other recommendations for research Referral of people who have diabetic foot problems |
| 16 17 18 19 20 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? Other recommendations for research Referral of people who have diabetic foot problems Within the hospital MDT, when is it appropriate and effective to refer people with |
| 16 17 18 19 20 21 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? Other recommendations for research Referral of people who have diabetic foot problems Within the hospital MDT, when is it appropriate and effective to refer people with diabetes who have foot problems to specialist services such as investigative or |
| 16 17 18 19 20 21 22 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? Other recommendations for research Referral of people who have diabetic foot problems Within the hospital MDT, when is it appropriate and effective to refer people with diabetes who have foot problems to specialist services such as investigative or interventional radiology, orthopaedic or vascular services, specialist pain |
| 16 17 18 19 20 21 22 23 | What is the clinical effectiveness of different dressing types in treating diabetic foot problems? Other recommendations for research Referral of people who have diabetic foot problems Within the hospital MDT, when is it appropriate and effective to refer people with diabetes who have foot problems to specialist services such as investigative or interventional radiology, orthopaedic or vascular services, specialist pain management and specialist orthotics? |

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| 1 | Review of people with diabetic foot problems | |
|----|---|--|
| 2 | How often should people with diabetic foot problems (foot ulcers, soft tissue | |
| 3 | infections, osteomyelitis or gangrene) be reviewed? | |
| 4 | Diabetic foot ulcer | |
| 5 | What is the clinical effectiveness of negative pressure wound therapy in the | |
| 6 | treatment of diabetic foot ulcers? | |
| 7 | Diabetic foot ulcer | |
| 8 | What is the clinical effectiveness of maggot debridement therapy in the debridement | |
| 9 | of diabetic foot ulcers? | |
| 10 | Charcot arthropathy | |
| 11 | Which risk stratification tools can be used to predict the likelihood of Charcot | |
| 12 | arthropathy? | |
| 13 | Charcot arthropathy | |
| 14 | When is it safe to stop contact casting in the treatment of acute Charcot arthropathy | |
| 15 | Rationale and impact | |
| 16 | These sections briefly explain why the committee made the recommendations and | |
| 17 | how they might affect practice. They link to details of the evidence and a full | |
| 18 | description of the committee's discussion. | |
| 19 | Treatment | |
| 20 | Recommendations <u>1.6.6 and 1.6.7</u> | |
| 21 | Why the committee made the recommendations | |
| 22 | The committee agreed that in people with diabetes all foot wounds are likely to be | |
| 23 | colonised with bacteria. However, for people with a <u>diabetic foot infection</u> , prompt | |
| 24 | treatment of the infection is important to prevent complications. The committee | |
| 25 | agreed to retain the recommendation from the 2015 guideline that antibiotics should | |
| 26 | be started as soon as possible if a diabetic foot infection is suspected. The choice of | |
| 27 | antibiotic would depend on the <u>severity of infection</u> , although the committee | |

acknowledged that the studies they looked at did not always differentiate between

28

- 1 severities. The committee accepted the Infectious Diseases Society of America's
- 2 definitions of mild, moderate and severe infection, and recommended that this
- 3 should be taken into account when choosing an antibiotic.
- 4 The committee retained the 2015 recommendation that samples should be taken for
- 5 microbiological testing before, or as close as possible to, the start of antibiotic
- 6 treatment. This would allow empirical antibiotic treatment to be changed if needed
- 7 when results are available.
- 8 How the recommendations might affect practice
- 9 This recommendation is consistent with current practice.
- 10 Full details of the evidence and the committee's discussion are in evidence review X:
- 11 title.
- 12 Return to recommendations
- 13 Choice of antibiotic, dose frequency, route of administration and
- 14 course length
- 15 Recommendations <u>1.6.8 to 1.6.11</u>
- 16 Why the committee made the recommendation
- 17 The evidence showed no difference in clinical outcomes for most antibiotics. But the
- antibiotics used in the studies were not wholly representative of UK practice, with
- 19 some not being available in the UK and others not widely used. There were no
- 20 differences in adverse events for many antibiotic comparisons. However, there were
- 21 differences between some antibiotic classes, with lower rates of adverse effects
- 22 generally for beta-lactam antibiotics.
- 23 The committee agreed, based on the evidence and their experience, that the choice
- of antibiotic should be based on severity of infection (mild, moderate or severe) and
- 25 the risk complications, while minimising adverse effects and antibiotic resistance.
- 26 This means using narrow spectrum antibiotics first, where possible, and using
- 27 microbiological results when available to guide treatment. Patient preference is also
- important, particularly for if treatment will involve a hospital stay or be prolonged.

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- 1 Diabetes is a chronic condition and people may have had previous foot infections,
- 2 with previous courses of antibiotics, that will influence their preferences.
- 3 No evidence was identified comparing antibiotic dose, frequency or route of
- 4 administration. However, the committee knew that a person with a diabetic foot
- 5 infection may already be on a number of other medications, and this should be taken
- 6 into account when deciding on dose, frequency and route of administration of an
- 7 antibiotic.
- 8 In line with the NICE guideline on antimicrobial stewardship and Public Health
- 9 England's Start smart then focus, the committee agreed that oral antibiotics should
- 10 be used in preference to intravenous antibiotics where possible. Intravenous
- antibiotics should only be used for people who are severely ill, unable to tolerate oral
- 12 treatment, or where oral treatment would not provide adequate coverage or tissue
- penetration. The use of intravenous antibiotics should be reviewed by 48 hours
- 14 (taking into account the person's response to treatment and any microbiological
- results) and switched to oral treatment where possible.
- 16 The committee agreed that a shorter course was generally as effective as a longer
- 17 course for adults with a mild diabetic foot infection, and a 7-day course was sufficient
- for most people. However, they agreed that a longer course (up to a further 7 days)
- may be needed for some people based on a clinical assessment of their symptoms
- and history. They discussed the limited evidence on antibiotic course length, which
- compared 6 weeks with 12 weeks in adults with diabetic foot osteomyelitis. The
- committee agreed that for people with a moderate or severe diabetic foot infection
- 23 (which includes osteomyelitis), a 7-day course would be a minimum, with antibiotic
- treatment for up to 6 weeks if people have osteomyelitis. When prolonged antibiotic
- 25 treatment is given, they recommended reviewing the need for continued antibiotics
- 26 regularly.

27

How the recommendations might affect practice

- 28 The recommendations aim to optimise antibiotic use and reduce antibiotic
- 29 resistance.
- 30 Full details of the evidence and the committee's discussion are in evidence review X:
- 31 title.

1 Return to recommendations

- 2 **Advice**
- 3 Recommendation <u>1.6.12</u>
- 4 Why the committee made the recommendations
- 5 The committee based the recommendation on their experience and safety netting
- 6 advice from the NICE guideline on antimicrobial stewardship. They agreed that if
- 7 symptoms worsened rapidly or significantly at any time, or did not improve within 2
- 8 to 3 days, people with a diabetic foot infection should be advised to seek medical
- 9 help.
- 10 How the recommendations might affect practice
- 11 The recommendations should ensure that appropriate safety netting is in place.
- 12 Full details of the evidence and the committee's discussion are in evidence review X:
- 13 <u>title.</u>
- 14 Return to recommendations
- 15 **Reassessment**
- 16 Recommendations 1.6.13 to 1.6.14
- 17 Why the committee made the recommendations
- 18 The committee agreed that when microbiological results are available, they should
- 19 be used to guide antibiotic choice. The committee also discussed factors that would
- 20 indicate that a person with a diabetic foot infection would need to be reassessed.
- 21 These included if an infection was rapidly or significantly worsening or not improving,
- 22 if other diagnoses were possible, or symptoms suggested a more serious illness or
- 23 condition.
- 24 How the recommendations might affect practice
- 25 This recommendations should ensure that appropriate reassessment is in place.
- 26 Full details of the evidence and the committee's discussion are in evidence review X:
- 27 <u>title.</u>

1 Return to recommendations

2 **Prevention**

- 3 Recommendation 1.6.15
- 4 Why the committee made the recommendations
- 5 The committee agreed to retain the 2015 recommendation that antibiotics should not
- 6 be given to prevent diabetic foot infections. No evidence was identified for antibiotic
- 7 prophylaxis and the committee agreed that antibiotic prophylaxis is not appropriate
- 8 because of concerns about antimicrobial resistance. People should be advised to
- 9 seek medical help if symptoms of a diabetic foot infection develop.
- 10 How the recommendations might affect practice
- 11 This recommendation is consistent with current practice.
- 12 Full details of the evidence and the committee's discussion are in evidence review X:
- 13 <u>title.</u>
- 14 Return to recommendations

15 **Context**

- 16 Diabetes is 1 of the most common chronic diseases in the UK and its prevalence is
- increasing. In 2013, there were almost 2.9 million people in the UK diagnosed with
- diabetes. By 2025, it is estimated that more than 5 million people in the UK will have
- 19 diabetes. In England, the number of people diagnosed with diabetes has increased
- 20 by approximately 53% between 2006 and 2013, from 1.9 million to 2.9 million. The
- 21 life expectancy of people with diabetes is shortened by up to 15 years, and 75% die
- 22 of macrovascular complications.
- 23 The risk of foot problems in people with diabetes is increased, largely because of
- 24 either diabetic neuropathy (nerve damage or degeneration) or peripheral arterial
- 25 disease (poor blood supply due to diseased large and medium sized blood vessels
- in the legs), or both. Peripheral arterial disease affects 1 in 3 people with diabetes
- over the age of 50, and can also increase the risk of heart attack and stroke. For
- 28 more information, see the NICE guideline on lower limb peripheral arterial disease.

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- 1 Foot complications are common in people with diabetes. It is estimated that 10% of
- 2 people with diabetes will have a diabetic foot ulcer at some point in their lives. A foot
- 3 ulcer can be defined as a localised injury to the skin and/or underlying tissue, below
- 4 the ankle, in a person with diabetes.
- 5 Diabetes is the most common cause of non-traumatic limb amputation, with diabetic
- 6 foot ulcers preceding more than 80% of amputations in people with diabetes. After a
- 7 first amputation, people with diabetes are twice as likely to have a subsequent
- 8 amputation as people without diabetes. Mortality rates after diabetic foot ulceration
- 9 and amputation are high, with up to 70% of people dying within 5 years of having an
- amputation and around 50% dying within 5 years of developing a diabetic foot ulcer.
- 11 This high mortality rate is believed to be associated with cardiovascular disease, and
- 12 emphasises the importance of good diabetic and cardiovascular risk management.
- 13 Although people of South Asian, African and African Caribbean family origin are
- more at risk of diabetes, there is no evidence that the prevalence of diabetic foot
- 15 ulceration and amputation is higher in these subgroups than in the general
- 16 population of people with diabetes in the UK.
- 17 Foot problems in people with diabetes have a significant financial impact on the NHS
- through primary care, community care, outpatient costs, increased bed occupancy
- 19 and prolonged stays in hospital. A report published in 2012 by NHS Diabetes
- 20 estimated that around £650 million (or £1 in every £150 the NHS spends) is spent on
- 21 foot ulcers or amputations each year.

Finding more information and resources

- 23 To find out what NICE has said on topics related to this guideline, see our web page
- 24 on diabetes.

22

25

Update information

- 26 March 2019
- 27 This guideline is an update of NICE guideline NG19 (published August 2015).
- 28 We have reviewed the evidence on antimicrobial prescribing for people with a
- 29 diabetic foot infection.

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1 Recommendations are marked [2019] if the evidence has been reviewed.

2 Recommendations that have been deleted or changed

- 3 We propose to delete some recommendations from the 2015 guideline. <u>Table 2</u> sets
- 4 out these recommendations and includes details of replacement recommendations.
- 5 If there is no replacement recommendation, an explanation for the proposed deletion
- 6 is given.
- 7 In recommendations shaded in grey and ending [2011] or [2015], we have not
- 8 reviewed the evidence.
- 9 See also the previous NICE guideline and supporting documents.

10 Table 2 Recommendations that have been deleted

| Recommendation in 2015 guideline | Comment |
|--|--|
| All hospital, primary care and community settings should have antibiotic guidelines covering the care pathway for managing diabetic foot infections that take into account local patterns of resistance (1.6.6) | This recommendation has been deleted because the updated recommendations, including the choice of antibiotics table, take into account antimicrobial resistance. |
| Choose the antibiotic treatment based on the severity of the diabetic foot infection, the care setting, and the person's preferences, clinical situation and medical history and, if more than 1 regimen is appropriate, select the regimen with the lowest acquisition cost (1.6.9) | Replaced by: When choosing an antibiotic for people with a suspected diabetic foot infection take account of: • the severity of diabetic foot infection (mild, moderate or severe) • the risk of developing complications • previous microbiological results • previous antibiotic use • patient preferences. [2019] (1.6.7) and information in the antibiotic prescribing table. |
| Decide the targeted antibiotic regimen for diabetic foot infections based on the clinical response to antibiotics and the results of the microbiological examination. (1.6.10) | Replaced by: When choosing an antibiotic for people with a suspected diabetic foot infection take account of: • the severity of diabetic foot infection (mild, moderate or severe) • the risk of developing complications • previous microbiological results • previous antibiotic use • patient preferences. [2019] (1.6.7) When microbiological results are available: |

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| | review the choice of antibiotic, and change the antibiotic according to results, using a narrow spectrum antibiotic, if appropriate. [2019] (1.6.13) and information in the antibiotic prescribing |
|--|--|
| | table |
| Do not offer tigecycline to treat diabetic foot infections unless other antibiotics are not suitable. (1.6.11) | Recommendation no longer needed because the antibiotic prescribing table contains all antibiotic options. |
| For mild diabetic foot infections, initially offer oral antibiotics with activity against gram-positive organisms. (1.6.12) | This recommendation has been deleted because the information is now contained within the antibiotic prescribing table. |
| Do not use prolonged antibiotic treatment (more than 14 days) for the treatment of mild soft tissue diabetic foot infections. (1.6.13) | This recommendation has been deleted because the information is now contained within the antibiotic prescribing table. |
| For moderate and severe diabetic foot infections, initially offer antibiotics with activity against gram-positive and gram-negative organisms, including anaerobic bacteria, as follows: | This recommendation has been deleted because the information is now contained within the antibiotic prescribing table. |
| Moderate infections: base the route of administration on the clinical situation and the choice of antibiotic. | |
| Severe infections: start with intravenous antibiotics and then reassess, based on the clinical situation. (1.6.14) | |
| Offer prolonged antibiotic treatment (usually 6 weeks) to people with diabetes and osteomyelitis, according to local protocols. (1.6.15) | This recommendation has been deleted because the information is now contained within the antibiotic prescribing table. |
| Start antibiotic treatment for suspected diabetic foot infection as soon as possible. Take cultures and samples before, or as close as possible to, the start of antibiotic treatment. (1.6.8) | Replaced by: Start antibiotic treatment for suspected diabetic foot infection as soon as possible. Take samples for microbiological testing before, or as close as possible to, the start of antibiotic treatment. (1.6.6) |
| Do not offer antibiotics to prevent diabetic foot infections. (1.6.7) | Replaced by: Do not offer antibiotics to prevent diabetic foot infections. Give advice about seeking medical help if symptoms of a diabetic foot infection develop. (1.6.15) |

1

2 Minor changes since publication

- 3 **[January 2016]:** Recommendation 1.3.6 has been updated to clarify the risk factors
- 4 for and stratification of risk of developing a diabetic foot problem.

- 1 [December 2015]: Recommendation 1.3.14 has been amended to refer to the
- 2 updated NICE guideline on type 2 diabetes in adults.
- 3 © NICE 2019. All rights reserved. Subject to Notice of rights.