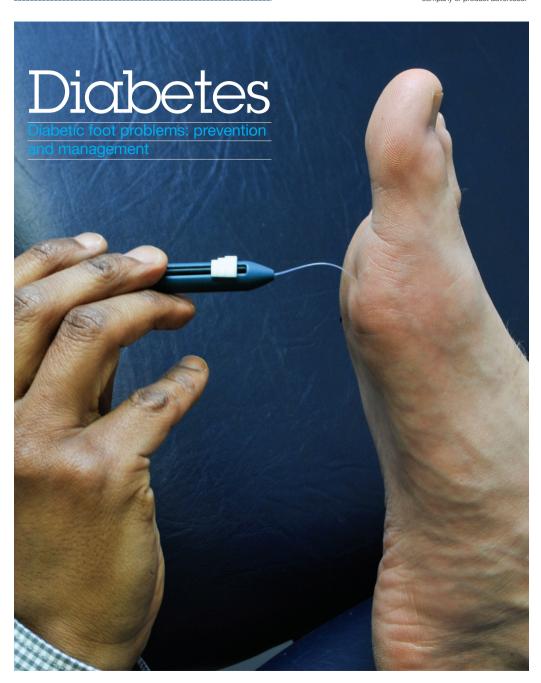
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# Welcome

This summary of guidance on Diabetic foot problems: prevention and management updates and replaces NICE guidelines CG10 (published January 2004) and CG119 (published March 2011), and the recommendations on foot care in NICE guideline CG15 (published July 2004). The full version of this guidance is available at www.nice.org.uk/quidance/ng19



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# Clinical guideline

iabetes is one of the most common chronic diseases in the UK with the number of UK patients expected to rise from 2.9m in 2013. to 5m by 2025. Diabetic

foot problems are a common and potentially serious complication associated with this chronic condition, and can lead to increased risk of surgical intervention and mortality.

A report published in 2012 by NHS Diabetes estimated that around £650 million (or £1 in every £150 the NHS spends) is spent on foot ulcers or amputations each year.

#### RECOMMENDATIONS

#### Care across all settings

Commissioners and service providers should ensure that the following are in place:

- A foot protection service for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community.
- · A multidisciplinary foot care service for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service. This may also be known as an interdisciplinary foot care service.
- Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including

- emergency care and general practice. The protocols should set out the relationship between the foot protection service and the multidisciplinary foot care service.
- Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit.

The foot protection service should be led by a podiatrist with specialist training in diabetic foot problems, and should have access to healthcare professionals with skills in the following areas:

- Diabetology.
- Biomechanics and orthoses.
- Wound care.

The multidisciplinary foot care service should be led by a named healthcare professional, and consist of specialists with skills in the following areas:

- Diabetology.
- Podiatry.
- Diabetes specialist nursing.
- Vascular surgery.
- Microbiology.
- Orthopaedic surgery.
- Biomechanics and orthoses.
- Interventional radiology.
- Casting.
- Wound care.

The multidisciplinary foot care service should have access to rehabilitation services, plastic surgery, psychological services and nutritional services.

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.

Take into account any disabilities, including visual impairment, when planning and delivering care for people with diabetes.

# ASSESSING THE BISK OF **DEVELOPING A DIABETIC FOOT PROBLEM**

#### Frequency of assessments

For children with diabetes who are under 12 years, give them, and their family members or carers (as appropriate), basic foot care advice.

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.

For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times:

- When diabetes is diagnosed, and at least annually thereafter.
- If any foot problems arise.
- On any admission to hospital, and if there is any change in their status while they are in hospital.

# Assessing the risk of developing a diabetic foot problem

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:

- Neuropathy (use a 10g 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.

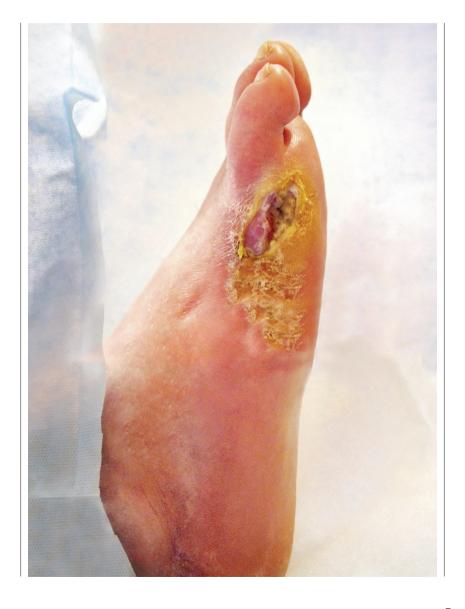
Use ankle brachial pressure index in line with the NICE guideline on lower limb peripheral arterial disease. Interpret results carefully in people with diabetes because calcified arteries may falsely elevate results.

Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification:

- · Low risk: no risk factors present.
- Moderate risk: 1 risk factor present.
- High risk: previous ulceration or amputation, on renal replacement therapy, or more than 1 risk factor present.
- Active diabetic foot problem: ulceration, spreading infection, critical ischaemia, gangrene, suspicion of an acute Charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain.

# Managing the risk of developing a diabetic foot problem

For people who are at low risk of developing a diabetic foot problem, continue to carry out annual foot assessments, emphasise the importance of foot care, and advise





them that they could progress to moderate or high risk.

Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service.

The foot protection service should assess newly referred people as follows:

- 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 diabetic foot problem.

For people at moderate or high risk of developing a diabetic foot problem, the foot protection service should:

- 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 provide specialist footwear and orthoses.

- 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.

Depending on the person's risk of developing a diabetic foot problem, carry out reassessments at the following intervals:

- Annually for people who are at low risk.
- Frequently (for example, every 3–6 months) for people who are at moderate
- 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.

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.

## Patient information about the risk of developing a diabetic foot problem

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:

• 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.
- Information about diabetes and the importance of blood glucose control (also see recommendation 1.3.14).

# DIABETIC FOOT PROBLEMS

#### Referral

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), 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:

- 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). 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.

## Patient information about diabetic foot problems

Provide information and clear explanations

as part of the individualised treatment plan. for people with a diabetic foot problem. Information should 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
- Information about diabetes and the importance of blood glucose control (also see recommendation 1.3.14).

If a person presents with a diabetic foot problem, take into account that they may have an undiagnosed, increased risk of cardiovascular disease that may need further investigation and treatment. For guidance on the primary prevention of cardiovascular disease, see the NICE guideline on lipid modification.

#### DIABETIC FOOT ULCER

#### Investigation

If a person has a diabetic foot ulcer, assess and document the size, depth and position of the ulcer.

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.

Do not use the Wagner classification system to assess the severity of a diabetic foot ulcer.

#### Treatment

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



- Offloading.
- · Control of foot infection.
- Control of ischaemia.
- Wound debridement.
- Wound dressings.

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.

In line with the NICE guideline on pressure ulcers, use pressure redistributing devices and strategies to minimise the risk of pressure ulcers developing.

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.

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.

Consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.

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.

Consider dermal or skin substitutes as an adjunct to standard care when treating diabetic foot ulcers, only when healing has not progressed and on the advice of the multidisciplinary foot care service.

Do not offer the following to treat diabetic foot ulcers, unless as part of a clinical trial:

- Electrical stimulation therapy, autologous platelet rich plasma gel, regenerative wound matrices and dalteparin.
- Growth factors (granulocyte colony stimulating factor [G CSF], platelet derived growth factor [PDGF], epidermal growth factor [EGF] and transforming growth factor beta [TGF ]).
- Hyperbaric oxygen therapy.

When deciding the frequency of follow up as part of the treatment plan, take into account the overall health of the person with diabetes, how healing has progressed, and any deterioration.

Ensure that the frequency of monitoring set out in the person's individualised treatment plan is maintained whether the person with diabetes is being treated in hospital or in the community.

#### DIABETIC FOOT INFECTION

### Investigation

If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a deep swab because it may provide useful information. on the choice of antibiotic treatment.

Consider an X ray of the person's

affected foot (or feet) to determine the extent of the diabetic foot problem.

Think about osteomyelitis if the person with diabetes has a local infection, a deep foot wound or a chronic foot wound.

Be aware that osteomyelitis may be present in a person with diabetes despite normal inflammatory markers, X rays or probe to bone testing.

If osteomyelitis is suspected in a person with diabetes but is not confirmed by initial X ray, consider an MRI to confirm the diagnosis.

#### Treatment

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.

Do not offer antibiotics to prevent diabetic foot infections. 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.

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.

Decide the targeted antibiotic regimen for diabetic foot infections based on the clinical response to antibiotics and the results of the microbiological examination.

Do not offer tigecycline to treat diabetic foot infections unless other antibiotics are not suitable.

For mild diabetic foot infections, initially offer oral antibiotics with activity against gram positive organisms.

Do not use prolonged antibiotic treatment (more than 14 days) for the treatment of mild soft tissue diabetic foot infections

For moderate and severe diabetic foot infections, initially offer antibiotics with activity against gram positive and gram negative organisms, including anaerobic bacteria, as follows:

- 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.

Offer prolonged antibiotic treatment (usually 6 weeks) to people with diabetes and osteomyelitis, according to local protocols.

#### CHARCOT ARTHROPATHY

#### Investigation

Be aware that if a person with diabetes fractures their foot or ankle, it may progress to Charcot arthropathy.

Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported.

To confirm the diagnosis of acute Charcot arthropathy, refer the person within 1 working day to the multidisciplinary foot care service for triage within 1 further working

day. Offer non weight bearing treatment until definitive treatment can be started by the multidisciplinary foot care service.

If acute Charcot arthropathy is suspected, arrange a weight bearing X ray of the affected foot and ankle. Consider an MRI if the X ray is normal but Charcot arthropathy is still suspected.

#### Treatment

If the multidisciplinary foot care service suspects acute Charcot arthropathy, offer treatment with a non removable offloading device. If a non removable device is not advisable because of the clinical, or the person's, circumstances, consider treatment with a removable offloading device.

Do not offer bisphosphonates to treat acute Charcot arthropathy, unless as part of a clinical trial.

Monitor the treatment of acute Charcot arthropathy using clinical assessment. This should include measuring foot-skin temperature difference and taking serial X rays until the acute Charcot arthropathy resolves. Acute Charcot arthropathy is likely to resolve when there is a sustained temperature difference of less than 2 degrees between both feet and when X ray changes show no further progression.

People who have a foot deformity that may be the result of a previous Charcot arthropathy are at high risk of ulceration and should be cared for by the foot protection service.

#### **RESOURCE**

The full, updated NICE guideline on Diabetic foot problems: prevention and management is available to view on the NICE website at: www.nice.org.uk/ guidance/ng17

#### Instructions for Use

### Allpresan® diabetic Foam Cream INTENSIVE

#### Intended purpose

Allpresan® diabetic Foam Cream INTENSIVE is a medical device for the specific treatment of very dry to chapped foot skin in patients with diabetes mellitus. Its special properties also make it suitable for the treatment of wound edges. Allpresan® diabetic Foam Cream INTENSIVE promotes the healing process and supports recovery of the damaged skin barrier.

The specially designed active formula forms a breathable, twodimensional protective coating. It strengthens the barrier function, protects against external impacts, and reduces mechanical stresses such as friction without impairing natural skin function. The skin is optimally supplied with moisture, and Pentavitin® also guards against moisture loss. Relieves itching, counteracts pressure marks, and also helps to prevent calluses.

Mornings and evenings, apply an amount about the size of a hazelnut or walnut to the affected areas of the feet. Also beneficial for use between the toes. Allpresan® diabetic Foam Cream offers excellent convenience in use, since it is very easy to rub in. It can be applied very quickly without leaving behind an unpleasant greasy film. There is reduced risk of slipping, and you can put on your stockings - even compression stockings - immediately after use. Shake well before each use, and hold the container upright when applying (please ensure the can is in the upright position and do not tilt during use!)



Never apply to the eye region or mucus membranes, or in open wounds. Do not use Allpresan® diabetic Foam Cream INTENSIVE once the expiration date has passed. For external use only

#### Contraindications



Do not use if there is known sensitivity to any of the ingredients. Do not use on infants or children under the age of 5 years.

#### Interactions



Urea can increase the release of other active ingredients from other external-use products, and promote their penetration into the skin. Please ask your doctor or pharmacist if you are using other external-use products.

#### Ingredients

Aqua, Urea, Butane, Decyl Oleate, Octyldodecanol, Cetearyl Alcohol, Propane, Stearic Acid, Propylene Glycol, Glycerin, Glyceryl Stearate, Panthenol, Saccharide Isomerate (Pentavitin®), Undecyl Alcohol, Allantoin, Potassium Lauroyl Wheat Amino Acids, Palm Glycerides, Capryloyl Glycine, Sodium Lauroyl Sarcosinate, Sodium Citrate, Citric Acid.

Pentavitin® made by Pentapharm Ltd.

#### Points to consider



Warning. Pressurised container: May burst if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. 9 % by mass of the contents are flammable. Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122°F. Keep out of reach of children. Use only in well-ventilated areas.

#### Instructions for Use

### Allpresan® diabetic Foam Cream BASIC

#### Intended purpose

Allpresan® diabetic Foam Cream BASIC is a medical device for the specific treatment of dry and sensitive foot skin in patients with diabetes mellitus. Its special properties also make it suitable for the treatment of wound edges. Allpresan® diabetic Foam Cream BASIC boosts the skin's barrier function, thus protecting against skin infections and ulcerations.

### **Properties**

The specially designed active formula forms a breathable, twodimensional protective coating. It strengthens the barrier function, protects against external impacts, and reduces mechanical stresses such as friction without impairing natural skin function. The skin is optimally supplied with moisture, and Pentavitin® also quards against moisture loss. Reduces roughness, counteracts pressure marks and smooths the skin.

Mornings and evenings, apply an amount about the size of a hazelnut or walnut to the affected areas of the feet. Also beneficial for use between the toes. Allpresan® diabetic Foam Cream offers excellent convenience in use, since it is very easy to rub in. It can be applied very quickly without leaving behind an unpleasant greasy film. There is reduced risk of slipping, and you can put on your stockings - even compression stockings - immediately after use. Shake well before each use, and hold the container upright when applying (please ensure the can is in the upright position and do not tilt during use!)

### Last update in:



Manufacturer: nsc Pharma GmbH & Co. KG • 48268 Greven, GERMANY

neubourg pharma (UK) Limited • Headley House • Parklands Queen Elizabeth Park • Railton RD • Guildford • Surrey, GU2 9JX • UK



Never apply to the eye region or mucus membranes, or in open wounds. Do not use Allpresan® diabetic Foam Cream BASIC once the expiration date has passed. For external use only.

#### Contraindications



Do not use if there is known sensitivity to any of the ingredients. Do not use on infants or children under the age of 5 years.

#### Interactions



Urea can increase the release of other active ingredients from other external-use products, and promote their penetration into the skin. Please ask your doctor or pharmacist if you are using other external-use products.

#### Ingredients

Aqua, Butane, Urea, Decyl Oleate, Octyldodecanol, Cetearyl Alcohol, Propane, Stearic Acid, Propy-lene Glycol, Glycerin, Glyceryl Stearate, Panthenol, Saccharide Isomerate (Pentavitin®), Undecyl Alcohol, Allantoin, Potassium Lauroyl Wheat Amino Acids, Palm Glycerides, Capryloyl Glycine, Sodium Lauroyl Sarcosinate, Sodium Citrate, Citric Acid.

Pentavitin® made by Pentapharm Ltd.

#### Points to consider



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Maximum storage





for use LOT Batch code

Consult instructions

Legend:







used between the toes

Allpresan

diabetic

FOAM CREAM

Dry and

BarrioExpert<sup>®</sup>

Foam Cream Technology

Allpresan

diobetic

FOAM CREAM

Very dry to chapped skin Allpresan<sup>®</sup> is the only clinically formulated foam cream to prevent dry cracked skin and calluses on diabetic feet<sup>1,2</sup>

- > Can be used on the entire foot, including between the toes<sup>3</sup>, unlike conventional creams
- > Boosts the skin's barrier function, thus protecting against skin infections and ulceration<sup>1,3-5</sup>
- Quick to apply, non-greasy and footware can be put on immediately after application<sup>3</sup>
- Lasts up to twice as long as conventional creams<sup>6</sup>

Also available to purchase at pharmacies nationwide and Diabetes UK online shop NHS price £5.50/125ml7

Neubourg Pharma (UK) Limited | Headley House, Parklands, Queen Elizabeth Park, Railton Road, Guildford, Surrey GU2 9JX 01483 238209 | info@neubourgpharma.com www.allpresan.uk.com

References: 1. Neubourg Pharma [UK] Ltd. Allpresan diabetic Foam Cream Basic. Available at http://allpresan.uk.com/wp-content/uploads/2014/08/Product-leaflet-Basic.pdf. Date accessed August 2015. 2. Neubourg Pharma [UK] Ltd. Allpresan diabetic Foam Cream Intensive. Available at http://allpresan.uk.com/wp-content/uploads/2014/08/Product-leaflet-Intensive.pdf. Date accessed August 2015. 3. Daniels R. Foam-creams. Effective skin care in patients with diabetes mellitus. Theme-Park Rep 2013.1151:12-14. A. Wigner-Albertif wit ed. Foot care in diabetes. Adequate care of try and sensitive skin for diabetic foot. Cosmer Med 2015;11(5):20-55. Neubourg Pharma [UK] Ltd. Data on file 001. 6. Neubourg Skin Care GmbH & Co. Expert report. Definition of the quantity applied of both products. Allpresan® Foam Cream. DT No.-8807/0727. Y. MIMS. Available at http://www.mims.co.uk/drugs/skin/careams-purfust-ary-skin-conditions/allpresan-diabetic-arceasesed-august 2015.