Acne Vulgaris: Management

Consultation on draft scope
Stakeholder comments table

24/09/2018 to 22/10/2018

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Alliance Pharmaceuticals.	7	32	The evidence base for Isotretinoin is well established as a systemic retinoid, used in secondary care, after topical options have failed. The evidence base for oral Isotretinoin has recently been comprehensively reviewed and summarised in the European Evidence-based (S3) Guideline for the Treatment of Acne (Nast et al J Eur Acad Dermatol Venereol. 2016 Aug;30(8):supplement 1. The authors reached the following conclusions:- "….*systemic isotretinoin should be considered as the first-choice treatment for severe acne, including high levels of clinical effectiveness, prevention of scarring and improvement of a patient's quality of life*."	Thank you for your comment and the reference provided.
Alliance Pharmaceuticals Ltd.	8	32	We believe that referral to secondary care is currently not optimal and subject to significant variation in practice. This is partly due to a lack of agreed assessment scales which consider both the physical and psychological impact of the condition. It is essential that clearer guidance is provided to primary care physicians to facilitate a standardised approach to the assessment of the physical severity of the condition and its psychological effect. This will help to guide more appropriate referral to secondary care dermatology. A recent review of assessment tools in acne (Agnew et al J Clin Aesthet Dermatol. 2016 Jul; 9(7): 40–52) demonstrated the lack of a gold standard, but the Leeds revised acne grading score is well known (O'Brien et al. J Dermatolog Treat. 1998;9:215–220), and guidance from the PCDS (http://www.pcds.org.uk/clinical-guidance/acne-vulgaris) both give simple pictorial guides, which could help to standardise assessment of physical severity We would suggest that a simple tool such as the Cardiff acne disability index (Motley et al Clin and Exp Dermatology. 1992;17:1-	Thank you for your comment. Section 3.6 of the scoping document covers the main outcomes. However, the specifics of how these outcomes would be measured will be discussed with the guideline committee when the details of the evidence reviews are planned. We will highlight the assessment tools you mention to the guideline committee at this time.

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			3) could be used in primary care to evaluate the psychological impact more effectively.	
British Association of Dermatologists	General	General	Hormone-modifying agents should include women with persistent/recurrent acne regardless of whether they have polycystic ovary syndrome (PCOS).	Thank you for your comment. We have revised the scope to combine key areas 6 and 7 related to hormonal contraceptive treatment and hormone modifying agents, and have removed reference to people with polycystic ovary syndrome to allow the possibility that hormone modifying agents are used for other people with acne vulgaris. People with polycystic ovary syndrome may then be considered as a subgroup when the details of the evidence review are planned with the guideline committee.
British Association of Dermatologists	General	General	This is a very broad agenda and it would be useful for the team to consider breaking it down to make this a practical guide for clinical use as the literature for each will be different and significant for individual areas. Possible areas: • Acne vulgaris defined as acne that may develop from around adrenarche (so allows for patients with earlier puberty) to an upper-defined age limit. • If including childhood acne suggest needs defining as very few studies have been done in children but appreciate the treatment recommendations for children may be different • Some unusual variants (could specify these, e.g. acne fulminans and include endocrinopathies if required) • Management in pregnancy and reproductive age Sequelae to include scars and possibly other sequelae as outlined below, etc.	Thank you for your comment. The final version of the guideline will include a visual representation of the topics covered and how they relate to each other, which can be used as a practical guide for clinicians and service users. The scope includes people from all age groups and therefore the first two bullet points in the comment could be included as a group in a pathway depending on the guideline committee discussion. In relation to bullet point three, acne conglobate and acne fulminans are both covered in the scope under key area 7. People who are pregnant and people with potential to become pregnant are important subgroups that we will look at (see section 3.1 in the scope). The scope does not cover specific investigations of endocrinopathies related to acne, but endocrine disorders may be a subgroup in key area 6 (related to hormonal contraceptive treatments and hormone modifying agents). However, we cannot at this stage pre-empt how the guideline and the visual representation will be structured as this will depend on discussions with the guideline committee and the specific evidence reviews conducted for the guideline.
British Association of Dermatologists	General	General	We would avoid introducing the concept of PCOS within the context of acne vulgaris *per se* – generally, females with acne have no evidence of biochemical hormonal abnormalities but over 40% get pre-menstrual flares and respond well to hormonal therapies –	Thank you for your comment. We have revised the scope to combine key areas 6 and 7 related to hormonal contraceptive treatment and hormone modifying agents, and have removed reference to people with polycystic ovary syndrome to allow the possibility that hormone modifying agents are used for other people

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			PCOS is a potential subgroup and patients may present with acne but within this subgroup there is a spectrum of PCOS which is challenging to diagnose in adolescents – recent new guidance makes reference to this. The PCOS literature is significant and therefore if going to include suggest that this is dealt with as a subsection in unusual variants.	with acne vulgaris and due to the challenges related to the diagnosis of polycystic ovary syndrome. People with polycystic ovary syndrome may then be considered as a subgroup when the details of the evidence review are planned with the guideline committee.
British Association of Dermatologists	General	General	If including acne scarring, which is another large area to search, we suggest post-inflammatory pigmentation should also be included as this is a significant issue for many patients especially with skin phototypes 4-5. If considering sequelae, a practical guide to psychosocial aspects / impacts of acne might be considered?	Thank you for your comment. We recognise the importance of altered pigmentation in relation to acne. The guideline committee may well include secondary prevention of this complication of acne as an outcome for therapies reviewed (and section 3.6 of the scope, 'Main outcomes' has been revised to include 'altered skin pigmentation'). It is not considered feasible within this scope to look at the wider and complex issue of treating altered pigmentation.
British Association of Dermatologists	General	General	Exclusion of babies less than 28 days – this cut-off is arbitrary so may wish to avoid stating this time frame – in reality, true neonatal acne can persist longer than 28 days.	Thank you for your comment. Babies under 28 days have now been removed from the list of groups that will not be covered, and we have added neonatal acne as an area that will not be covered.
British Association of Dermatologists	General	General	We would avoid the concept of "hygiene" as this sounds as if acne may be due to poor hygiene, a myth that needs to be addressed – suggest use the term "skin care" an important area that is frequently neglected in acne treatment regimes.	Thank you for your comment. We have reworded this key area to 'skin care advice'.
British Association of Dermatologists	General	General	In our previous response we encouraged the development of some really practical guidelines that could be adopted in clinical practice and would provide practitioners with the best advice on implementing active therapy within the context of a chronic disease, i.e. over time, so providing a treatment algorithm within the context of a guidelines including how to manage relapses and maintaining improvement once control is gained. This would align with judicious use of antibiotics and current policies on avoidance of antimicrobial resistance. Some of the newest international guidelines have considered common clinical scenarios to support better prescribing over time.	Thank you for your comment. All NICE guidelines have an associated 'pathway' that can be used as a practical and visual guide for clinicians and service users. For some guidelines, a separate treatment algorithm is produced but whether this guideline will have one will be determined at a later stage during guideline development in consultation with the guideline committee.

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British Association of Dermatologists	General	General	Challenges to consider: - 1. any systematic review of the evidence should factor in older, but very relevant studies, e.g. those on benzoyl peroxide 2. efficacy studies use many different outcome measures making comparisons between studies and treatments difficult 3. most efficacy studies are in a specific population and done over a relatively short period of time not reflecting the nature of the disease there is currently no up-to-date data on antibiotic resistance patterns across the U.K. and there is still no evidence to confirm the relative benefits of anti-inflammatory effects of antibiotics vs. antimicrobial effects	Thank you for your comment. We will highlight these challenges to the guideline committee when the protocols for the specific evidence reviews that will be conducted for the guideline are discussed. We have highlighted in the 'Policy, legislation, regulation and commissioning' section of the scoping document that this guideline will take into account the national and international principles of antimicrobial guidance and policy as outlined in both the NICE guideline Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use, and the WHO's Global action plan on antibiotic resistance. Antibiotics are commonly used for acne and reviewing this will be an opportunity to address this topic in a way that respects the principles of antimicrobial stewardship. As part of developing this guideline the committee will consider both evidence on the effectiveness of antimicrobial interventions and national data on antimicrobial resistance patterns from the English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR) in line with the way that NICE produces Antimicrobial Prescribing Guidelines. We have also added antimicrobial resistance as an outcome to section 3.6 of the scope.
British Association of Dermatologists	General	General	Some Trusts have introduced the concept of supporting clinicians and patients about choice and decision-making it would be useful to consider what is needed as well as what is valued in section 13. This could align well with practical information on when to escalate treatment and consider referral from both clinician and patient perspective – an implementation tool and possible decision aid would make this guideline unique and practical to use.	Thank you for your comment. We have phrased the draft review question in terms of what is valued by people with acne, and their parents or carers, to indicate that we are planning to carry out a systematic review of qualitative evidence. Such a review would explore the views and perceptions of people with acne, which may include what they feel they need to know. The exact details of the review question will be determined through discussion with the guideline committee when the protocols are being finalised.
British Association of Dermatologists	General	General	Stakeholders: 1. British Society for Paediatric Dermatology 2. Primary Care Dermatological Society 3. Verity-PCOS 4. Young People's Health Special Interest Group	Thank you for your comment. We will check the list of registered stakeholders and invite them to register if they are not already.

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British Association of Dermatologists	General	Key issue 8	Oral corticosteroids for the treatment of acne conglobate and acne fulminans should be a bit broader to cover other aspects of management of these conditions, e.g. use of high-dose antibiotics, dapsone and steroid injections.	Thank you for your comment. Acne conglobate and acne fulminans are severe forms of acne vulgaris and may therefore be considered in other topic areas where applicable. However, a specific focus on the use of corticosteroids for these severe forms was thought important as these would not be used for less severe forms.
British Association of Dermatologists	General	Key issue 9	Isotretinoin for acne should also be broader to include initiation, dose peak, duration and concomitant treatments to prevent flares.	Thank you for your comment. The scope identifies broad areas of the treatments for acne vulgaris that will be covered in the guideline (see Section 3.3), whilst Section 3.5 covers the proposed draft review questions relevant to these areas. The precise details of the review question which will be specified in the relevant protocol will be determined in the early stages of development through discussion with the guideline committee, and we will raise the issues you provide at this stage. It may therefore be the case that some of the issues you raise relating to the use of isotretinoin may be addressed in the guideline depending on the committee's view on which issues are important to prioritise. Please be aware that, as the treatment of acne is complex and wide ranging, it will not be possible to address every detail of each treatment. The committee will therefore prioritise those areas with the widest variation in current practice.
British Society for Medical Dermatology	6	16	Acne is in most cases a benign self-limiting disorder. However, as outlined in the introduction, in some cases it can cause significant loss of quality of life (QOL) by the impact on mental health and or physical health. Permanent scarring may result in some cases. Nevertheless, because the majority of cases are self-limiting without a loss of QOL, one option that should be discussed in most consultations is the option of no treatment. For clinicians to better place the other draft questions in the context of a no treatment option, I would suggest adding a further question(s): 'what is the risk of loss of quality of life in acne vulgaris sufferers and which clinical parameter best predicts the group with the greatest loss?'	Thank you for your comment. It is very likely that a 'placebo' and/or 'no treatment' comparator will be included in the relevant evidence reviews. Regarding your suggested questions, quality of life and emotional wellbeing are included as main outcomes in the guideline (see Section 3.6 in the scoping document). Hence the effect of an intervention compared to placebo on these outcomes will be addressed in the relevant questions. While we agree that knowing which clinical parameters best predict reduced quality of life or impaired mental health is an important topic they are not directly linked to acne management. Quality of life and mental health would not necessarily be only related to acne but are influenced by many other factors. As such, our review questions will cover the relative effect of an intervention compared to a comparator (e.g. no treatment) on quality of life and emotional wellbeing. The scoping group agreed however, that risk factors for scarring

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			'what is the risk of impaired mental health in acne vulgaris sufferers and which clinical parameter best predicts the group with the greatest harm?' 'what is the risk of facial / other site scarring in acne vulgaris sufferers and which clinical parameter best predicts the group with the greatest harm?'	resulting from acne vulgaris should be prioritised because this would have a direct impact on acne management. It has therefore been added as a new key area to the scope.
Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit	General	General	The scope covers the appropriate areas of relevance to us, including use of hormonal contraception for acne management and contraceptive considerations for women with potential to become pregnant while using other acne treatments (particularly those that are teratogenic). We hope that NICE will align with MHRA recommendations re contraception when using teratogens – we understand that the MHRA are currently finalising their pregnancy prevention programme at present and we encourage the NICE guideline development group to look at this.	Thank you for your comment. The guideline committee will bear recommendations by the Medicines & Healthcare products Regulatory Agency in mind when drafting the recommendations.
NHS England	1	24	Acne can have a serious impact on the patient's quality of life and I would also add this impact is not just cosmetic but can be **psychological** at a time of developing and fragile self-esteem and also those with moderate to severe lesions can experience considerable physical pain	Thank you for your comment. Quality of life and emotional wellbeing are included as two of our main outcomes (see section 3.6 of the scoping document which lists the main outcomes). The more specific outcomes for evidence reviews (which could include pain where applicable) will be determined through discussion with the guideline committee when the protocols are developed.
NHS England	3	14-15	Could the first line treatment options i.e. hygiene and topical be provided by pharmacy rather than GP? This would provide a support to GPs struggling with capacity if they could sign post patients to pharmacy, perhaps a PGD could be developed?	Thank you for your comment. We will discuss the evidence related to these topics in the scope with the guideline committee and they will then draft recommendations. At this stage, we are not able to pre-empt whether they will indicate who should prescribe treatments.
NHS England	8	1-30	Many if not all of the physical treatments listed are cosmetic and outside the scope of the NHS and would be expected to be accessed privately by the patient, NICE guidance on this would provide clarity and support to GPs	Thank you for your comment. NICE guidelines can recommend both treatments that should be prescribed by healthcare professionals and treatments that healthcare professionals may advise patients to access themselves.

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Royal College of General Practitioners	General	General	To recognise the relative persistence and the burden in women into later adult life and later onset in females https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935648/	Thank you for your comment. We do not have an upper age limit and therefore women in later life who have acne are included in the guideline scope. Although we will look for evidence on late-onset acne, how much can be said about this specific group in the final guideline will depend on the available evidence.
Royal College of General Practitioners	General	General	It is important to consider UK NHS waiting lists for dermatology (for oral retinoids) and other European policy on prescribing these drugs	Thank you for your comment. We will raise this issue with the guideline committee when the evidence for, and any recommendations relating to, oral retinoids is discussed.
Royal College of General Practitioners	General	General	There is relative dvt risk (if any) of drugs such as dianette and yasmin	Thank you for your comment. One of our main outcomes is 'adverse effects of treatment', which is intentionally broad because the specifics of these 'adverse effects' will vary by treatment. We will raise the issue with the guideline committee of whether deep vein thrombosis should be an adverse effect of interest when the protocol associated with hormonal contraceptives (key issue 6) is discussed and finalised.
Royal College of General Practitioners	General	General	There is risks of combination therapy with oral tetracylines with oral contraceptives	Thank you for your comment. We will raise this issue with the guideline committee when the protocols associated with oral antibiotics and hormonal contraceptives treatments (key issues 3 to 6) are discussed.
Royal College of General Practitioners	General	General	Consider if there any role for topical antibiotics	Thank you for your comment. Topical antibiotics will be addressed by the evidence available on topical treatments (key issue 2 in the scoping document). The guideline committee will decide whether or not to recommend the use of topical antibiotics for acne vulgaris whilst respecting the principles of antimicrobial stewardship.
Royal College of General Practitioners	General	General	It is important to take into account the reduce antibiotic generally policies	Thank you for your comment. We have highlighted in the 'Policy, legislation, regulation and commissioning' section of the scope that the guideline will take into account the national and international principles of antimicrobial guidance and policy as outlined in the NICE guideline Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use, and the WHO's Global action plan on antibiotic resistance. As part of developing this guideline the committee will consider both evidence on the effectiveness of antimicrobial interventions and national data on

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				antimicrobial resistance patterns from the English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR) in line with the way that NICE produces Antimicrobial Prescribing Guidelines. We have also added antimicrobial resistance as an outcome to section 3.6 of the scope.
Royal College of General Practitioners	General	General	Recognise the use of pharmacists and buying treatment over the counter OTC to reduce overall NHS costs- and Pharmacy training	Thank you for your comment. As detailed in the 'Policy, legislation, regulation and commissioning' section of the scoping document, NHS resource use is an important factor that will be taken into consideration by the guideline committee when making recommendations. NHS England has, for this reason, advised Clinical Commissioning Groups (CCGs) that a prescription for treatment of mild acne should not routinely be offered in primary care as it is appropriate for self-care (see the NHS document Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs [2018]).
Royal College of General Practitioners	General	General	Recognise the use of apps by young people with acne such as MDacne	Thank you for your comment. The use of electronic applications that provide information and support will be considered in key issue 13 of the scope. If use of the application involves treatment (such as the MDacne benzoyl peroxide topical cream), then whether or not it should be used will be determined by the evidence for the relevant key areas. For example, if MDacne provides users with access to micronized benzoyl peroxide topical cream, then this will also be related to the questions on topical treatments (key issue 2). Note that at this stage we cannot pre-empt whether or not the use of electronic applications will be recommended because this depends on the evidence and guideline committee's interpretation of it.
Royal College of General Practitioners	General	General	To consider the issues of treatment of acne in people with Down's syndrome	Thank you for your comment. As part of guideline development recommendations are drafted that will apply to all people who experience acne vulgaris. This would include people with physical as well as cognitive disabilities. NICE has an obligation to advance equality related to health and social care, and the guideline committee discuss issues related to equality when drafting their recommendations (these may for instance include specific recommendation related to treatments that require complex instructions or that are difficult to administer by people who have complex physical disabilities). Please see also the Equalities Impact Assessment form that outlines the details

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				of how this guideline will address specific equality considerations related to acne vulgaris.
Royal College of Nursing	General	General	The Royal College of Nursing (RCN) welcomes proposals to develop NICE guidelines for the management of Acne Vulgaris. The RCN invited members who care for people with acne to review the draft document and provide comments on our behalf. The following comments reflect the views of our reviewers.	Thank you for your comment.
Royal College of Nursing	General	General	It is essential that the *prevention* of scarring is considered.	Thank you for your comment. Scarring is included as one of the main outcomes that will be considered in this guideline (see section 3.6 in the scoping document). This has been reworded from 'reduction of scarring' to 'scarring', and therefore prevention may be addressed in the relevant questions.
Royal College of Nursing	General	General	We need to be mindful of the increasing number of women for whom acne remains or appears in adulthood and guidance on how they might be better supported.	Thank you for your comment. Equality issues relating to this population will be considered by the guideline committee
Royal College of Nursing	General	General	We suggest that the guideline developers make reference to the *Acne Priority Setting Partnership*. The Partnership was set up to identify and rank treatment uncertainties by bringing together people with acne and the healthcare professionals providing their care within and beyond the National Health Service. (Layton A, et al 2015) British Medical Journal (BMJ) Open 2015; 5:e008085. doi:10.1136/bmjopen-2015-008085	Thank you for your comment. We will raise this issue with the guideline committee when the questions in the scope are discussed and finalised.
Royal College of Nursing	3	18	"Darker skin colour"? Would the terms "across the range of skin colours be more inclusive"?	Thank you for your comment. We kept the terminology 'darker skin colour' because post inflammatory pigmentation impacts people with darker skin. Fair skinned people do not get this problem as they cannot produce sufficient melanin in their skin, so the post inflammatory pigmentation does not occur across 'a range of skin colours'. This is described in further detail in the equality impact assessment form.

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				The wording 'darker skin colour' is also consistent with the wording used in the NICE guidance on sunlight and skin.
Royal College of Paediatrics and Child Health	General	General	The scope has covered the most important points	Thank you for your comment.
Royal College of Paediatrics and Child Health	General	General	The scope is not excluding any important clinical groups	Thank you for your comment.
Royal College of Paediatrics and Child Health	General	General	The scope is asking the right questions	Thank you for your comment.
Royal College of Paediatrics and Child Health	General	General	The respondent is happy with the scope	Thank you for your comment.
Royal College of Paediatrics and Child Health	General	General	It is counter intuitive for diagnosis and prevention to not be considered	Thank you for your comment. It was decided that the variation in practice in the diagnosis of acne vulgaris is not as wide as in the management of the condition, which was therefore prioritised in the commissioning of this guideline. Even though primary prevention was not prioritised in the scope 'prevention of relapse' may be included as an outcome for some evidence reviews if the guideline committee think that this would be appropriate when planning the reviews.
Royal College of Paediatrics and Child Health	General	General	If the diagnosis is incorrect then the rest of the diagnosis is potentially harmful	Thank you for your comment. It was decided that the variation in practice in the diagnosis of acne vulgaris is not as wide as in the management of the condition, which was therefore prioritised in the commissioning of this guideline.
Royal College of Paediatrics and Child Health	General	General	Prevention is better than cure, illness prevention and self-help are corner stones of the modern NHS	Thank you for your comment. Although primary prevention was not prioritised in the scope, 'scarring' has been included as one of the main outcomes that will be considered in this guideline (see section 3.6 in the scoping document). Prevention of scarring will thus be addressed in the relevant questions. 'Prevention of relapse' may be included as an outcome for some evidence

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				reviews if the guideline committee think that this would be appropriate when planning the reviews. However, it was decided that there is more variation in practice, and more evidence available, in relation to the management of acne and this was therefore prioritised in the commissioning of this guideline.
Royal College of Pathologists	General	General	The draft scope does not include a consideration of the evidence linking antibiotics used in the management of acne vulgaris to the development of antimicrobial resistance (AMR). Given the global importance of AMR, the potential for topical and oral treatments, either as sole treatment agents or in combination with other therapy, to promote and facilitate the spread of resistance should be considered in the deliberations of the NICE guidelines group when assessing the benefits of antibiotic treatment of acne vulgaris.	Thank you for your comment. We have highlighted in 'Policy, legislation, regulation and commissioning' section of the scoping document that the guideline will take into account the national and international principles of antimicrobial guidance and policy, as outlined in the NICE guideline Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use, and the WHO's Global action plan on antibiotic resistance. Antibiotics are commonly used for acne and reviewing this will be an opportunity to address this topic in a way that respects antimicrobial stewardship. As part of developing this guideline the committee will consider both evidence on the effectiveness of antimicrobial interventions and national data on antimicrobial resistance patterns from the English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR) in line with the way that NICE produces Antimicrobial Prescribing Guidelines. We have also added antimicrobial resistance as an outcome to section 3.6 of the scope.
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Association of Dermatologists (BAD).	Thank you for your comment.
The British Society for Antimicrobial Chemotherapy (BSAC)	General	General	Members of The British Society for Antimicrobial Chemotherapy (BSAC) have no comments for the **Guideline: Acne Vulgaris: Management (Jan 2021)**	Thank you for your comment.

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Willingsford Ltd.	General	General	Acapsil is a novel first-in-class wound dressing based on micropore particle technology (MPPT). MPPT consists of small highly porous particles. The physical properties of these particles result in a system that by passive capillary evaporation removes exudate on the wound surface. This micro-pumping process in parallel removes the toxins and enzymes secreted by bacteria and fungi into the wound to inhibit the immune cells and it creates holes in the biofilm that bacteria and fungi secrete as a shield against the immune cells. The result is that MPPT disrupts the weaponry of bacteria and fungi, whereby the immune cells regain their ability to selectively remove bacteria and fungi and become able to create the balance the immune system seeks in the microbiome, i.e. the ecosystem of bacteria, fungi, viruses and mites that live on our external surfaces and form part of our protection against the outside environment. It is unbalances in this microbiome that interfere with healing and is expressed as infection. Newer data have shown that the skin has its own dedicated immune system, which demonstrates the importance of this barrier for protecting the integrity of the body and maintaining skin health (1). The micro-pumping effects of MPPT automatically stop when the excess exudate has been removed and the particles will retain a certain moisture levels, thus preventing over-drying of the wound surface. MPPT has no antimicrobial effects, but it has repeatedly been seen to remove wound infections and facilitate the healing of difficult wounds – including wounds that did not respond to standard antimicrobials, negative pressure wound therapy (NPWT), honey and absorbent dressings.	Thank you for your comment. The guideline committee will consider a range of topical treatments for acne and will decide on those that will be included in the evidence reviews when the details of the reviews are planned. We cannot pre-empt the body of evidence that we will look for so we are unable to comment on whether the studies mentioned in the comment will be included.

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			As MPPT lacks antimicrobial effects, its use will not lead to the generation of antimicrobial resistance and its effects will not be limited by resistance. A review of MPPT, its mode-of-action and its use in wound healing has been accepted for publication in the US journal WOUNDS (2) and is scheduled to appear in their November issue: "Sams-Dodd J, Sams-Dodd F (2018) Time to abandon antimicrobial approaches in wound healing – a paradigm shift. WOUNDS, November issue." MPPT has been evaluated in a comparative clinical study with 266 patients covering a range of wound types (3). The study found that the use of MPPT resulted in an infection-free and healing wound 60% quicker compared to a topical antibiotic (gentamicin) and an antiseptic (iodine) and that MPPT on average reduced the number of hospitalisation days by 31%. The reduction in hospitalisation days by MPPT compared to gentamicin was 41% for acute wounds (includes dehisced surgical wounds, abscesses, furuncles and carbuncles), 31% for diabetic foot ulcers and 19% for venous leg ulcers. A clinical audit was performed at Bristol University Hospital, covering 9 acute dehisced surgical wounds and 1 category 4 pressure ulcer (4). MPPT was able to induce a clean healing wound in 3-5 days. All wounds reached closure. Standard-of-care at the hospital is 1 week with UrgoClean followed by 2 or more weeks with NPWT to reach the same state of healing as was achieved by 3-5 days with MPPT. Health economic calculations indicate that MPPT resulted in savings of 67% to reach the healing wound state, when compared to the 1 week with UrgoClean and 2 weeks with NPWT. With respect to the category 4 pressure ulcer, several treatment	

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			approaches had already been tried but without success before the use of MPPT. Lovgren et al. (2018) presented a poster on MPPT in 3 cases of stable, inactive pyoderma gangrenosum ulcers at the British Association for Dermatology meeting in Edinburgh July 3-5 (5). In all 3 cases, once daily application of MPPT for 5 consecutive days led to a change in the ulcer such that they continued to improve even after 2-3 months after application. In one case, it was possible to reduce the dose of immunosuppressant. MPPT has also demonstrated positive effects in other wound types such as a pilonidal sinus, which was not responding to standard approaches including repeated surgery and NPWT; acute and chronic venous leg ulcers; a 3-year-old diabetic foot ulcer; and a 35-year-old radiation induced abscess. A short video of a nonhealing pressure ulcer can be seen here: https://www.youtube.com/channel/UCdY3srLHCM9sKGvzd8LT31w. Briefly, MPPT was used in community care on a 9-week-old deep pressure ulcer with two sinuses and undermining. Hydrogel, Manuka honey and Flaminal Forte combined with packing had been tried and failed. MPPT was after 3 applications able to advance the ulcer towards healing. Estimated savings were 89%. MPPT has been used on additional acute and chronic pressure ulcers in the UK and comparable effects have been reported. For case reports please see: http://acapsil.com/en-gb/. MPPT has not been associated with any wound irritation or allergy. It has been used directly on exposed tendon and bone and for prolonged periods of time.	

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			In summary, MPPT has demonstrated the ability to advance the healing of wounds and ulcers, including ulcers that normally would be characterised as dermatological conditions. Its effects do not rely on any antimicrobial actions and it will consequently not contribute to the generation of AMR. NICE in a 2015 review of wound dressings for infected wounds and the FDA in an executive summary in 2016 (6) have concluded that there is no consistent evidence to demonstrate that dressings containing antibiotic and antiseptics remove wound infections or support healing. Furthermore, Sams-Dodd and Sams-Dodd (2) have demonstrated why antimicrobial approaches are ineffective and why they should be replaced with approaches that interact with the skin and wound microbiome to normalise the microbiome. The latter approach also has the advantage that it will not contribute to the creation of AMR, which both antibiotics and antiseptics do (7,8), and it avoids the cytotoxicity at clinical concentrations which is typical of antiseptics and which will damage the generation of new tissue aiming to heal a lesion. Moist wound care is often used in wound care, but infection is considered the likeliest single cause of delayed healing for wounds and ulcers (9) and newer data have shown that moist wound care is likely to exacerbate an infection (10,11,12). In cases, where delayed healing or risks of infection are present, it is therefore not optimal. Acne vulgaris generally involves lesions of varying severity, and while the cause of the lesion may be different to wounds and ulcers, once skin breakage and local infection have occurred, the physiological processes towards healing are the same. Acapsil has demonstrated consistent and strong effects in wound healing, including carbuncles and furuncles, an infected nonhealing pilonidal	

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			sinus and in a severe dermatological condition such as pyoderma gangrenosum; it will consequently also be effective on lesions caused by acne and it will have the advantage that it does not rely on antimicrobial properties and will not contribute to AMR. In terms of use in acne, Acapsil is a powder that is applied topically to the lesion once daily for 1-3 days. Costs will be low as one bottle of 750 mg priced at £65+VAT will cover at least 50 sq.cm of skin. A lesion will typically be around 0.5 by 0.5 cm, i.e. 0.25 sq.cm, which means that one bottle will be sufficient for 200 applications. The bottles are approved for multiapplication and for direct sales to laypersons. MPPT has not been associated with any adverse events and it has been applied to intact skin for several days without causing any negative effects. Several studies have linked acne vulgaris to changes in the skin microbiome (13,14) and it has been reported that the effects of retinoids (15) in acne is presided by a change in the microbiome, thereby indicating a causal relationship. Data indicate that Acapsil supports wound healing by interacting with the skin microbiome and it is therefore possible that it may have additional effects on acne itself in addition to its effects on lesions, but data remain to be collected to study this relationship. In light of the new scientific knowledge that wound infections and support of healing should not be based on antimicrobial approaches but instead by interacting with the skin microbiome, it would seem relevant to include this information in a new guideline for acne vulgaris.	

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