National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Certolizumab pegol for treating moderate to severe plaque psoriasis [ID1232]

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	Cambridge University Hospitals NHSFT	Yes, it would be appropriate.	Comment noted. No action required.
	Eli Lilly and Company	Yes	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	We consider the proposed appraisal appropriate.	Comment noted. No action required.
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	As this drug is similar in action to other established anti-TNFs, is there much point in appraising what is essentially a 'me too' drug? Biosimilar availability, is also likely to offer greater opportunity for patient access to anti-TNFs, unless there is significant different data, that goes beyond what is already known about anti-TNFs to support an appraisal, perhaps allowing clinicians	Comments noted. Certolizumab pegol is not a biosimilar and cannot be appraised as such. Please see NICE's position

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		and patients to decide which of these similar drugs is most appropriate (if the costs are the same) would be more useful?	statement on evaluating biosimilar medicines. No action required.
	Psoriasis Association	Psoriasis is a condition that is very unique to each individual, and a treatment that works for one person may not necessarily work for another. Because of this, the Psoriasis Association is in favour of the widest possible variety of appropriate treatments being available to patients.Therefore, it is our feeling that a NICE appraisal of this treatment is appropriate.	Comments noted. No action required.
	UCB	UCB agree that an appraisal of certolizumab pegol (Cimzia®; CZP) through the STA process is appropriate for NICE to be able to expedite timely access to a clinically and cost effective technology. Cimzia® is currently indicated in Europe for the treatment of rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA). Cimzia® is currently recommended by NICE for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, including non-radiographic axial spondyloarthritis Due to the strong links with Psoriatic Arthritis (PsA) it is important to have alternative treatment options to treat the broader spectrum of Psoriatic disease. Many patients don't respond or lose response to currently available biologic therapies. A recent prospective observational study of drug survival from the British Association of Dermatologists Biologics Intervention Register (BADBIR) involving four commonly used biologic therapies revealed an overall survival rate in the first year of 77%, but by the third year this had fallen to 53%. Additional treatment options are beneficial for this chronic, lifelong disease (reference below). *Warren et al Differential Drug Survival of Biologic Therapies for the Treatment of Psoriasis: A Prospective Observational Cohort Study from the*	Comments noted. No action required.

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		British Association of Dermatologists Biologic Interventions Register (BADBIR)Journal of Investigative Dermatology (2015) 135, 2632–2640 UCB believe there remains significant unmet need for patients with psoriatic disease. Patients with psoriasis frequently suffer with mental health and well-being problems such as depression and anxiety. Additionally, there are increased risks of cardiovascular disease & many patients with Psoriasis (PSO) subsequently develop PsA with painful joints & extra articular manifestations.	
Wording	Cambridge University Hospitals NHSFT	Yes, it does. This is a high cost drug. Once started and if effective, the patient is likely to be the drug for several years or lifelong.	Comment noted. No action required.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	There is no clear definition of “moderate to severe plaque psoriasis”. Our understanding is that the Phase III studies of certolizumab pegol in plaque psoriasis recruited patients with psoriasis area and-severity index (PASI) score of 12 or higher, Investigator’s Global Assessment [IGA] score of 3 or higher and involvement of 10% or more of the body-surface area.[1-3] The population for whom evidence on the clinical efficacy of certolizumab pegol is available, is therefore closely aligned to the populations included in studies of secukinumab and other biologic agents.[4-7] Whilst secukinumab and other biologic agents have marketing authorisation for treatment of moderate to severe plaque psoriasis,[8-13] NICE recommendations for these products refer to severe disease.[14-18] We therefore suggest that the appraisal should focus on patients with severe psoriasis.	Comments noted. NICE acknowledges that there are varying definitions of disease severity in psoriasis. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation. No action required.

		References 1. NCT02346240; https://clinicaltrials.gov/ct2/show/NCT02346240. Last accessed 29th September 2017. 2. NCT02326272; https://clinicaltrials.gov/ct2/show/NCT02326272. Last accessed 29th September 2017. 3. NCT02326298; https://clinicaltrials.gov/ct2/show/NCT02326298. Last accessed 29th September 2017. 4. Langley RG, Elewski BE, Lebwohl M, Reich K, Griffiths CE, Papp K, Puig L, Nakagawa H, Spelman L, Sigurgeirsson B, Rivas E. Secukinumab in plaque psoriasis—results of two phase 3 trials. *New England Journal of Medicine.* 2014 Jul 24;371(4):326-38. 5. Menter A, Tyring SK, Gordon K, Kimball AB, Leonardi CL, Langley RG, Strober BE, Kaul M, Gu Y, Okun M, Papp K. Adalimumab therapy for moderate to severe psoriasis: a randomized, controlled phase III trial. *Journal of the American Academy of Dermatology*. 2008 Jan 31;58(1):106-15. 6. Gottlieb AB, Evans R, Li S, Dooley LT, Guzzo CA, Baker D, Bala M, Marano CW, Menter A. Infliximab induction therapy for patients with severe plaque-type psoriasis: a randomized, double-blind, placebo-controlled trial. *Journal of the American Academy of Dermatology.* 2004 Oct 31;51(4):534-42. 7. Leonardi CL, Kimball AB, Papp KA, Yeilding N, Guzzo C, Wang Y, Li S, Dooley LT, Gordon KB, PHOENIX 1 Study Investigators. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). *The Lancet.* 2008 May 23;371(9625):1665-74. 8. European Medicines Agency (EMA). Cosentyx 150 mg powder for solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003729/WC500183129.pdf. Last accessed 29th September 2017.	

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		9. European Medicines Agency (EMA). Humira 40 mg solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000481/WC500050870.pdf.Last accessed 29th September 2017. 10. European Medicines Agency (EMA). Enbrel 25 mg powder for solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000262/WC500027361.pdf. Last accessed 29th September 2017. 11. European Medicines Agency (EMA). Remicade 100 mg powder for concentrate for solution for infusion. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000240/WC500050888.pdf. Last accessed 29th September 2017. 12. European Medicines Agency (EMA). Stelara 45/90 mg solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000958/WC500058513.pdf. Last accessed 29th September 2017. 13. European Medicines Agency (EMA). Taltz 80 mg solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003943/WC500205804.pdf. Last accessed 29th September 2017. 14. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA350). Secukinumab for treating moderate to severe plaque psoriasis (2015). Available at	

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		https://www.nice.org.uk/guidance/ta350. Last accessed 29th September 2017. 15. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA146). Adalimumab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta146. Last accessed 29th September 2017. 16. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA103). Etanercept and efalizumab for the treatment of adults with psoriasis (2006). Available at https://www.nice.org.uk/guidance/ta103. Last accessed 29th September 2017. 17. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA180). Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009). Available at https://www.nice.org.uk/guidance/ta180. Last accessed 29th September 2017. 18. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA442). Ixekizumab for treating moderate to severe plaque psoriasis (2017). Available at https://www.nice.org.uk/guidance/ta442. Last accessed 29th September 2017.	
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	Comment noted. No action required.
	UCB	Yes the draft scope wording is appropriate.	Comment noted. No action required.

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Timing Issues	Cambridge University Hospitals NHSFT	Urgent	Comment noted. NICE has scheduled this topic into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta10240. No action required.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	We suggest that this appraisal is not urgent, given that NICE has previously approved multiple TNF-alpha inhibitors for plaque psoriasis[15,16,19] in addition to newer agents, such as secukinumab,[14] which offer greater efficacy than subcutaneously administered TNF-alpha inhibitors.[20] **References** 14. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA350). Secukinumab for treating moderate to severe plaque psoriasis (2015). Available at https://www.nice.org.uk/guidance/ta350. Last accessed 29th September 2017. 15. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA146). Adalimumab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta146. Last accessed 29th September 2017.	Comments noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required.

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		16. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA103). Etanercept and efalizumab for the treatment of adults with psoriasis (2006). Available at https://www.nice.org.uk/guidance/ta103. Last accessed 29th September 2017. 19. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA134). Infliximab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta134. Last accessed 13th October 2017. 20. Loos, A. M., et al. "COMPARATIVE EFFECTIVENESS OF TARGETED IMMUNOMODULATORS FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS." VALUE IN HEALTH. Vol. 20. No. 5. 360 PARK AVE SOUTH, NEW YORK, NY 10010-1710 USA: ELSEVIER SCIENCE INC, 2017	
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	No urgency	Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required.
	Psoriasis Association	We do not feel that the timing of this appraisal is urgent, owing to there being existing drugs targeting the same pathway, with a similar dosing regime.	Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the

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			marketing authorisation for a technology is granted. No action required.
	UCB	Awaiting licence, [redacted]	Comments noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required.
Additional comments on the draft remit	-	-	-

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Cambridge University Hospitals NHSFT	The information appears to be accurate and complete.	Comment noted. No action required.
	Celgene	NICE guidance for dimethyl fumarate should be included (TA475).	Comment noted. The scope has been

Section	Consultee/ Commentator	Comments [sic]	Action
			updated to reflect the published NICE guidance on dimethyl fumarate for treating moderate to severe plaque psoriasis.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	No comment.	Comment noted. No action required.
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	Comment noted. No action required.
	UCB	Psoriatic disease is a relatively new term that encompasses the complexity that comes with the various manifestations of tissue and organ involvement in psoriasis patients. One of the principles of psoriasis management as listed in the 2016 WHO global report on psoriasis, is treating the whole person beyond the skin manifestations. This includes screening for the presence of early joint symptoms. Up to 29% of patients with PsO will develop PsA. *World Health Organization. Global report on psoriasis.* *Available from:* *http://apps.who.int/iris/bitstream/10665/204417/1/9789241565189_eng.pdf* *Accessed October 17, 2017*	Comments noted. No action required.

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		(Drugs. 2014 Mar;74(4):423-41. doi: 10.1007/s40265-014-0191-y.Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis.) *Ann Rheum Dis 2013;72:736-740. High prevalence of psoriatic arthritis in patients with severe psoriasis with suboptimal performance of screening questionnaires. Haroon M, Kirby B, FitzGerald O.* There is a significant burden of treatment for patients with PSO. Many patients remain dissatisfied with their treatment options and this can result in adherence issues. A recent survey demonstrated that patients receiving topical treatment for psoriasis were significantly least satisfied whereas patients receiving biologic treatment were significantly most satisfied. *British Journal of Dermatology: Satisfaction with treatment among patients with psoriasis: a web-based survey study, O.D. van Cranenburgh,, J. de Korte, M.A.G. Sprangers, M.A. de Rie, E.M.A. Smets* Many patients don't respond or lose response to currently available biologic therapies. A recent prospective observational study of drug survival from the British Association of Dermatologists Biologics Intervention Register (BADBIR) involving four commonly used biologic therapies revealed an overall survival rate in the first year of 77%, but by the third year this had fallen to 53%. Additional treatment options are beneficial for this chronic, lifelong disease. *Warren et al Differential Drug Survival of Biologic Therapies for the Treatment of Psoriasis: A Prospective Observational Cohort Study from the British Association of Dermatologists Biologic Interventions Register (BADBIR)Journal of Investigative Dermatology (2015) 135, 2632–2640*	

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		It has been recognised that the age of onset of the disease has two peaks, one between 20 & 30 years of age and another between the ages of 50 & 60, as such PSO particularly affects young & older working age people which further increases economic burden. I*ncidence, prevalence and mortality of patients with psoriasis: a UK population-based cohort study. D.A Springate et al BJD 22nd August 2016* *Expert Rev. Pharmacoecon. Outcomes Res. 14(5), 685-705 (2014). The economic burden of psoriasis: a systematic literature review. Feldman et al.* Although clinical studies and treatment goals are essentially based on addressing the skin manifestations of the disease, psoriasis is associated with a range of co-morbid conditions including inflammatory arthritis in the form of psoriatic arthritis, increased risk of cardiovascular co-morbidities; including myocardial infarction and stroke, and metabolic syndrome, diabetes, chronic renal insufficiency and occasionally liver abnormalities. *J Am Acad Dermatol 2017;76:377-90. Psoriasis and comorbid diseases. Epidemiology. Takeshita J et al.* Mehta and colleagues demonstrated psoriasis may shorten life expectancy by up to 5 years due to associated co-morbidities. *Am J Med 2011; 124 (8):775. Attributable risk estimate of severe psoriasis on major cardiovascular events. Mehta N et al.* Although certolizumab pegol, etanercept, adalimumab and infliximab all act by blocking the action of TNF, these drugs possess distinct characteristics in terms of their structure, mechanism of action and pharmacokinetic properties, which may explain the differential response rates. These factors	

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		may also explain why failure to respond to one TNF antagonist does not preclude responsiveness to another. *Clin Exp Rheumatol 2010; 28 (Suppl. 59):S5-S12. Development of TNF inhibitor therapies for the treatment of rheumatoid arthritis. Furst D.E.* *Rheumatology 2012;51:v22-v30. Optimizing outcomes in patients with rheumatoid arthritis and an inadequate response to anti-TNF treatment. Paul Emery.* In the UK, the British Association of Dermatologists (BAD) guidelines for the management of PSO state that biologic therapy should be considered earlier in the treatment pathway (for example, if methotrexate has failed, is not tolerated or is contra-indicated) in people with psoriasis that fulfil the disease severity criteria and who also have active psoriatic arthritis or who have psoriasis that is persistent (i.e. that relapses rapidly off a therapy that cannot be continued long-term.) *British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. C.H. Smith, et al. Br J Dermatol 2017; 177: 628-136*	
The technology/ intervention	Cambridge University Hospitals NHSFT	Yes.	Comment noted. No action required.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	No comment.	Comment noted. No action required.

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	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	Comment noted. No action required.
	UCB	Certolizumab pegol is a recombinant humanised antibody Fab' fragment against tumour necrosis factor-alpha (TNF‑alpha) and is conjugated to polyethylene glycol (PEG).	Comment noted. No action required.
Population	Cambridge University Hospitals NHSFT	The population defined is appropriate. I cannot think of any further populations to include.	Comment noted. No action required.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	We recommend that the wording is changed from “people” to “adults” with moderate to severe plaque psoriasis as we understand that only people aged 18 years or over were recruited into the Phase III studies of certolizumab pegol in plaque psoriasis.[1-3] There is no clear definition of “moderate to severe plaque psoriasis”. Our understanding is that the Phase III studies of certolizumab pegol in plaque psoriasis recruited patients with psoriasis area and-severity index (PASI) score of 12 or higher, Investigator’s Global Assessment [IGA] score of 3 or higher and involvement of 10% or more of the body-surface area.[1-3] The population for whom evidence on the clinical efficacy of certolizumab pegol is available, is therefore closely aligned to the populations included in studies of secukinumab and other biologic agents.[4-7] Whilst secukinumab and other biologic agents have marketing authorisation for treatment of moderate to severe plaque psoriasis,[8-13] NICE recommendations for these	Comment noted. The wording has been amended to “adults”. Comments noted. NICE acknowledges that there are varying definitions of disease severity in psoriasis. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation. No action required.

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		products refer to severe disease.[14-18] We therefore suggest that the appraisal should focus on patients with severe psoriasis. **References** 1. NCT02346240; https://clinicaltrials.gov/ct2/show/NCT02346240. Last accessed 29th September 2017. 2. NCT02326272; https://clinicaltrials.gov/ct2/show/NCT02326272. Last accessed 29th September 2017. 3. NCT02326298; https://clinicaltrials.gov/ct2/show/NCT02326298. Last accessed 29th September 2017. 4. Langley RG, Elewski BE, Lebwohl M, Reich K, Griffiths CE, Papp K, Puig L, Nakagawa H, Spelman L, Sigurgeirsson B, Rivas E. Secukinumab in plaque psoriasis—results of two phase 3 trials. *New England Journal of Medicine.* 2014 Jul 24;371(4):326-38. 5. Menter A, Tyring SK, Gordon K, Kimball AB, Leonardi CL, Langley RG, Strober BE, Kaul M, Gu Y, Okun M, Papp K. Adalimumab therapy for moderate to severe psoriasis: a randomized, controlled phase III trial. *Journal of the American Academy of Dermatology*. 2008 Jan 31;58(1):106-15. 6. Gottlieb AB, Evans R, Li S, Dooley LT, Guzzo CA, Baker D, Bala M, Marano CW, Menter A. Infliximab induction therapy for patients with severe plaque-type psoriasis: a randomized, double-blind, placebo-controlled trial. *Journal of the American Academy of Dermatology.* 2004 Oct 31;51(4):534-42. 7. Leonardi CL, Kimball AB, Papp KA, Yeilding N, Guzzo C, Wang Y, Li S, Dooley LT, Gordon KB, PHOENIX 1 Study Investigators. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). *The Lancet.* 2008 May 23;371(9625):1665-74.	

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		8. European Medicines Agency (EMA). Cosentyx 150 mg powder for solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003729/WC500183129.pdf. Last accessed 29th September 2017. 9. European Medicines Agency (EMA). Humira 40 mg solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000481/WC500050870.pdf.Last accessed 29th September 2017. 10. European Medicines Agency (EMA). Enbrel 25 mg powder for solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000262/WC500027361.pdf. Last accessed 29th September 2017. 11. European Medicines Agency (EMA). Remicade 100 mg powder for concentrate for solution for infusion. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000240/WC500050888.pdf. Last accessed 29th September 2017. 12. European Medicines Agency (EMA). Stelara 45/90 mg solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000958/WC500058513.pdf. Last accessed 29th September 2017. 13. European Medicines Agency (EMA). Taltz 80 mg solution for injection. Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-	

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		_Product_Information/human/003943/WC500205804.pdf. Last accessed 29th September 2017. 14. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA350). Secukinumab for treating moderate to severe plaque psoriasis (2015). Available at https://www.nice.org.uk/guidance/ta350. Last accessed 29th September 2017. 15. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA146). Adalimumab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta146. Last accessed 29th September 2017. 16. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA103). Etanercept and efalizumab for the treatment of adults with psoriasis (2006). Available at https://www.nice.org.uk/guidance/ta103. Last accessed 29th September 2017. 17. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA180). Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009). Available at https://www.nice.org.uk/guidance/ta180. Last accessed 29th September 2017. 18. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA442). Ixekizumab for treating moderate to severe plaque psoriasis (2017). Available at https://www.nice.org.uk/guidance/ta442. Last accessed 29th September 2017.	

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	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	Comment noted. No action required.
	UCB	Populations are defined appropriately.	Comment noted. No action required.
Comparators	AbbVie	This section should read (in line with the relevant published NICE TA guidance as follows): If systemic non-biological treatment or phototherapy is suitable: • Systemic non-biological therapies including methotrexate, ciclosporin, acitretin • Phototherapy with or without psoralen If systemic non-biological treatment or phototherapy is inadequately effective, not tolerated or contraindicated: • TNF-alpha inhibitors (adalimumab, etanercept) • Dimethyl fumarate • Ixekizumab • Secukinumab • Ustekinumab • Apremilast Best supportive care is not a comparator since in the absence of certolizumab these patients would receive a different drug treatment not best supportive care.	Comments noted. The comparators have been amended to reflect published NICE guidance on dimethyl fumarate for treating moderate to severe plaque psoriasis; Brodalumab for treating moderate to severe plaque psoriasis and Guselkumab for treating moderate to severe plaque psoriasis . In circumstances where phototherapy, systemic non-biological and biological therapies are not options, best supportive care is a valid comparator. No action required.

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	Cambridge University Hospitals NHSFT	Comparators are appropriate, comprehensive, and include the treatments commonly used in clinical practice.	Comment noted. No action required.
	Celgene	DMF should only be listed as a comparator in severe psoriasis post-conventional therapy in accordance with the NICE Guidance. FAEs are not relevant comparators in the non-biologic systemic therapies as they are unlicensed and there is great variation in their use across the UK. Celgene has NHIS data to support low usage. Best Supportive Care should only be included as a comparator post biologic or when biologics are contraindicated or not tolerated, i.e. it is not a relevant comparator for severe psoriasis patients who are eligible for biologics.	Comments noted. The comparators have been amended to reflect published NICE guidance on dimethyl fumarate for treating moderate to severe plaque psoriasis; Brodalumab for treating moderate to severe plaque psoriasis and Guselkumab for treating moderate to severe plaque psoriasis In circumstances where phototherapy, systemic non-biological and biological therapies are not options, best supportive care is a valid comparator. No action required.
	Eli Lilly and Company	Infliximab is a relevant comparator and ought to be included.	Comments noted. Infliximab is

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		Brodalumab, guselkumab and tildrakizumab are currently undergoing a NICE appraisal; therefore these may also be relevant comparators. Given the level of disease severity in the population eligible to receive certolizumab pegol and the recent expansion of treatment options for these patients, BSC may not be a relevant comparator in the economic evaluation.	recommended for very severe psoriasis and has been excluded from the comparators. Brodalumab and guselkumab have been added to the list of comparators. In circumstances where phototherapy, systemic non-biological and biological therapies are not options, best supportive care is a valid comparator. No action required.
	Novartis Pharmaceuticals UK Ltd	The appraisal of dimethyl fumarate in moderate to severe plaque psoriasis is no longer ongoing but was published on 6th September 2017.[21] The recommendations for dimethyl fumarate in TA475 are aligned to previous NICE technology appraisal guidance.[14-18] Dimethyl fumarate should therefore be included as a comparator in the population for whom systemic non-biological treatment or phototherapy is inadequately effective, not tolerated or contraindicated. For patients with very severe psoriasis (as defined by a total PASI score of 20 or more and a DLQI score of more than 18) infliximab should be included as an additional comparator alongside the other biologic therapies. **References**	Comments noted. The scope including the list of comparators have been updated to reflect the published NICE guidance on dimethyl fumarate for treating moderate to severe plaque psoriasis. Infliximab is recommended for very severe psoriasis and has been excluded from

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		14. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA350). Secukinumab for treating moderate to severe plaque psoriasis (2015). Available at https://www.nice.org.uk/guidance/ta350. Last accessed 29th September 2017. 15. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA146). Adalimumab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta146. Last accessed 29th September 2017. 16. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA103). Etanercept and efalizumab for the treatment of adults with psoriasis (2006). Available at https://www.nice.org.uk/guidance/ta103. Last accessed 29th September 2017. 17. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA180). Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009). Available at https://www.nice.org.uk/guidance/ta180. Last accessed 29th September 2017. 18. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA442). Ixekizumab for treating moderate to severe plaque psoriasis (2017). Available at https://www.nice.org.uk/guidance/ta442. Last accessed 29th September 2017. 21. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA475). Dimethyl fumarate for treating moderate to severe plaque psoriasis (2017). Available at	the comparators. No action required.

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		https://www.nice.org.uk/guidance/ta475. Last accessed 29th September 2017.	
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	Comment noted. No action required.
	Psoriasis Association	Phototherapy with or without psoralen is no longer a standard comparator as there are increasing areas of the country where phototherapy is no longer available, or it is not prescribed to patients as the time commitment means it is inaccessible. These are the standard treatments currently used in the NHS, although as a number of biosimilars are now available these may also need to be considered. The availability and costs of biosimilars should certainly be taken into account, however as individual treatments themselves. The British Association of Dermatologists recommends that patients are not 'switched' from original biologic to its related biosimilar. Therefore, their availability and cost can only be considered an alternative at treatment commencement - not during treatment. Best supportive care for those in whom biologics are contraindicated or not tolerated is likely to be systemic non-biologics. However, one of the reasons to progress to biologics is contraindication and tolerability issues at the systemic non-biologic stage. Therefore, for a significant proportion of patients, best supportive care will mean topical therapy, possibly including an in-patient stay.	Comments noted. Phototherapy is available and has been retained as a comparator. Comments noted. The scope states that the availability and cost of biosimilars of the comparators should be taken into account. No action required.
	UCB	In line with the BAD recommendations, we understand standard of care (pathway before biologics) to be ciclosporin or methotrexate. UCB will submit evidence versus comparators licenced in PSO and recommended appropriately in the treatment pathway.	Comments noted. The listed comparators are in line with the NICE

Section	Consultee/ Commentator	Comments [sic]	Action
			pathway for Psoriasis. No action required.
Outcomes	AbbVie	We would suggest that this section should read as follows: The outcome measures to be considered include: • severity of psoriasis • improvement of nail, high impact / difficult to treat sites (including face & scalp) and joint outcomes • mortality • response rate • duration of response • relapse rate • adverse effects of treatment • health-related quality of life.	Comments noted. The scope captures all the listed outcomes. No action required.
	Cambridge University Hospitals NHSFT	Yes, they do.	Comment noted. No action required.
	Eli Lilly and Company	The impact of certolizumab pegol on joints has already been assessed in NICE TA445 (Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs (2017)). We would suggest that joints be removed as an outcome measure to align the scope for certolizumab pegol with that of previous appraisals in psoriasis.	Comments noted. The outcomes in the scope have been kept broad for consideration if evidence allows.

Section	Consultee/ Commentator	Comments [sic]	Action
	Novartis Pharmaceuticals UK Ltd	In general the outcomes specified are appropriate, although we have the following comments: • Consideration of certolizumab pegol's benefits in treating psoriasis symptoms on the face, scalp and nails would require additional studies adequately powered to detect statistically significant differences between interventions on these outcomes. • Since joint symptoms are a comorbidity indicating presence of another condition, and are not measured in psoriasis trials, we do not consider them relevant to an economic assessment in psoriasis. • Duration of response is not an endpoint of psoriasis trials. Therefore we consider it may be more appropriate to measure outcomes at specific timepoints (e.g. 52 weeks) • Given the short-term nature of most clinical studies in psoriasis, we consider it unlikely that adequate data to support mortality endpoints will be available.	Comments noted. The outcomes in the scope have been kept broad for consideration if evidence allows.
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Measure of improvement should be seen as at least PASI 90 or clearance, as there are agents which are now showing these levels and adding another drug which does not improve on these, would appear a little pointless.	Comment noted. Minimal clinically important differences for outcomes will be considered within the appraisal. No action required.
	UCB	As noted in previous appraisal scoping, nail, scalp, feet involvement are important considerations of psoriasis, while comparative data may be limited, their significance should be considered beyond the PASI score.	Comments noted. No action required.

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		It is important to recognise increasing data suggests the use of TNF inhibitors may be associated with reduced risk of adverse cardiovascular events in preliminary epidemiologic studies. The option of additional TNFs may offer further value in supporting the broader clinical management of patients over the lifetime of treatment management that many PSO patients will require. *Current Pharmaceutical Design, 2014, 20, 500-512* *Effects of Biologic Agents and Other Disease-Modifying Antirheumatic Drugs on Cardiovascular Outcomes in Psoriasis and Psoriatic Arthritis: A Systematic Review* *April W. Armstrong1,*, Elizabeth A. Brezinski1,2, Matthew R. Follansbee1 and Ehrin J. Armstrong3* Patient Reported Outcomes (PROs) are critically important to understanding the outcomes of a treatment. Studies utilizing these measures have shown PSO to have a considerable impact on quality of life. Patients suffer from pain, fatigue, limitations to physical function and disability, as well as experiencing effects on their psychological, social and emotional well-being. Depression and anxiety are common and affect roughly one third of AS patients. The reported prevalence for depression in PSO varies substantially according to criteria used – 19% in the following using DSM IV: *Dowlatshahi EA. Journal of Investigative Dermatology. 2014;134:1542–1551.* Furthermore, impairment due to the disease on workplace activities and within household have also been reported.	

Section	Consultee/ Commentator	Comments [sic]	Action
		Indian J Dermatol Venereol Leprol. 2006 Jan-Feb;72(1):37-40.Evaluation of functional impairment in psoriasis.Gaikwad R1, Deshpande S, Raje S, Dhamdhere DV, Ghate MR. *Am J Clin Dermatol. 2009;10(6):407-10. doi: 10.2165/11310440-000000000-00000. Impact of psoriasis on patients' work and productivity: a retrospective, matched case-control analysis. Wu Y, Mills D, Bala M.* *Quality of Life and Work Productivity Impairment among Psoriasis Patients: Findings from the National Psoriasis Foundation Survey Data 2003–2011* *April W. Armstrong et al. Published: December 28, 2012* Approximately half of all patients with skin diseases particularly experience symptoms of itch and fatigue and a quarter experience these symptoms as relatively severe. These physical symptoms have relatively strong correlations with quality of life and disease severity. As such treatment needs to appropriately focused to manage these symptoms. *Br J Dermatol. 2007 Jun;156(6):1346-9.Prevalence of physical symptoms of itch, pain and fatigue in patients with skin diseases in general practice. Verhoeven EW* https://www.ncbi.nlm.nih.gov/pubmed/17535233	
Economic analysis	Cambridge University Hospitals NHSFT	It is important that economic analyses incorporate the current discounted price of biosimilar etanercept for use in psoriasis, and the anticipated discounted price of biosimilar adalimumab when it becomes available in Europe on 18 October 2018.	Comment noted. The scope states that the availability and cost of biosimilars of the comparators should be taken into account. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	No comment.	Comment noted. No action required.
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	No comments	Comment noted. No action required.
	UCB	List price of comparators will be utilised as the base case. In addition, a sensitivity analysis will be done on publicly available pricing information. UCB suggests a lifetime time horizon due to the chronic nature of PSO and, consequently, the lifelong nature of its treatment and associated costs.	Comments noted. No action required.
Equality and Diversity	Cambridge University Hospitals NHSFT	These NICE criteria are met.	Comment noted. No action required.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	No comment.	Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	No comments	Comment noted. No action required.
Innovation	Cambridge University Hospitals NHSFT	The technology is innovoative. However given that there are several effective comparators, the technology may not be a significant additional step-change in the management of psoriasis. Its efficacy is comparable with other already approved agents such as adalimumab and etanercept. As in RA and PsA, the technology does have the potential to offer a theoretically safe option in pregnant patients with psoriasis, as the lack of a Fab fragment in Cimzia significantly (though not entirely) reduces its placental transfer to the embryo / foetus. I am not aware of any substantial new evidence for the comparator technology/ies that have not been considered, or any important ongoing trials reporting in the next year.	Comments noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required.
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	Since NICE has already approved multiple TNF-alpha inhibitors for plaque psoriasis[15,16,19] in addition to newer agents, such as secukinumab,[14] which offer greater efficacy than subcutaneously administered TNF-alpha inhibitors,[20] , we do not consider certolizumab pegol will constitute a “step-change” in management of the condition **References** 14. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA350). Secukinumab for treating moderate to severe plaque psoriasis (2015). Available at	Comment noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		https://www.nice.org.uk/guidance/ta350. Last accessed 29th September 2017. 15. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA146). Adalimumab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta146. Last accessed 29th September 2017. 16. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA103). Etanercept and efalizumab for the treatment of adults with psoriasis (2006). Available at https://www.nice.org.uk/guidance/ta103. Last accessed 29th September 2017. 19. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA134). Infliximab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta134. Last accessed 13th October 2017. 20. Loos, A. M., et al. "COMPARATIVE EFFECTIVENESS OF TARGETED IMMUNOMODULATORS FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS." VALUE IN HEALTH. Vol. 20. No. 5. 360 PARK AVE SOUTH, NEW YORK, NY 10010-1710 USA: ELSEVIER SCIENCE INC, 2017.	

Section	Consultee/ Commentator	Comments [sic]	Action
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	No	Comment noted. No action required.
	Psoriasis Association	No	Comment noted. No action required.
	UCB	**Molecule** The addition of the PEG part of the certolizumab pegol molecule increases the stability and half-life of certolizumab pegol, PEGylation may also aid retention in inflamed tissue. In addition, pre-clinical and clinical data suggest a lack of active placental transfer of certolizumab pegol which may be the consequence of the absence of an Fc region. **Drug Survival – Unmet Need** There is a need for additional, innovative treatments for psoriasis as evidenced by data examining the real-world effectiveness of the currently available biologics. For example, Warren et al showed that drug survival fell to 53% by the 3rd year of biologic treatment, indicating a need for additional, effective treatment options. *Warren et al Differential Drug Survival of Biologic Therapies for the Treatment of Psoriasis: A Prospective Observational Cohort Study from the British Association of Dermatologists Biologic Interventions Register (BADBIR)Journal of Investigative Dermatology (2015) 135, 2632–2640*	Comments noted. Innovation will be considered by the appraisal committee when formulating its recommendations. The company will have an opportunity to provide evidence on the innovative nature of its product in its submission. No action required.
Other considerations	Cambridge University Hospitals NHSFT	Consideration must be given to the loading doses required by Cimzia, and how this will impact on clinical care of the patients (logistics) and cost for the period between initiation of therapy and assessment of efficacy determining continued treatment. The loading doses may make Cimzia significantly more	Comments noted. No action required.

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		expensive compared with the comparator agents, unless a free of charge or discounted provision of Cimzia is provided by the manufacturer. As in PsA and RA, I would expect Cimzia, to be an option for pregnant patients, and those who have not responded to a first TNFi in the form of adalimumab. I do not believe there will be barriers to the adoption of Cimzia into clinical practice, as it is already NICE-approved and used for rheumatoid arthritis and psoriatic arthritis. It is on most hospital formularies already. A single technology appraisal for Cimzia is appropriate.	
	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	No comment	Comment noted. No action required.
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	None	Comment noted. No action required.
	UCB	Evidence will be submitted to support the populations considered and any relevant subgroups, if relevant, in line with the licenced population. In line with the STA process, the cost effectiveness analysis will be in line with the population and comparators identified, aimed to address the cost-effectiveness of certolizumab pegol in the identified relevant populations.	Comments noted. No action required.

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		Highlighted by the British Association of Dermatologists Guidelines for biologic therapy for psoriasis (April 2017), psoriasis commonly affects men and women planning pregnancy and women who are pregnant and so understanding the risks of biologic therapy during conception, pregnancy and breast feeding is crucial. Guidelines on prescribing biologic therapy in people with rheumatic disease (BSR BHPR, EULAR) have been published this year (2016) and provide valuable summary information and consensus recommendations. *Flint J, Panchal S, Hurrell A et al. BSR and BHPR guideline on prescribing drugs in pregnancy and breastfeeding-Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids. Rheumatology (Oxford) 2016; **55**:1693-7.* *Gotestam Skorpen C, Hoeltzenbein M, Tincani A et al. The EULAR points to consider for use of antirheumatic drugs before pregnancy, and during pregnancy and lactation. Ann Rheum Dis 2016; **75**:795-810.*	
Questions for consultation	Eli Lilly and Company	No comment	Comment noted. No action required.
	Novartis Pharmaceuticals UK Ltd	Is certolizumab pegol expected to be an alternative treatment in the non-biological, or biological therapy part of the psoriasis treatment pathway, or both? *Novartis: Since certolizumab pegol is a biologic therapy, we expect it to be an alternative treatment in the biological therapy part of the psoriasis treatment pathway.* Have all relevant comparators for certolizumab pegol been included in the scope? *Novartis: See comments above on "comparators". On the basis that best supportive care has been included as a comparator in all previous*	Comments noted. No action required. In circumstances where phototherapy, systemic non-biological and biological therapies are not options, best supportive care is a valid comparator. No

Section	Consultee/ Commentator	Comments [sic]	Action
		appraisals of technologies for severe plaque psoriasis, we consider it appropriate that it is also included amongst the comparators for certolizumab pegol. Are the outcomes listed appropriate? *Novartis: See comments above on "Outcomes".* Are the subgroups suggested in 'other considerations appropriate? *Novartis: Nothing further to add beyond previous comments that moderate and severe psoriasis are poorly defined, and that for adults with very severe psoriasis, infliximab should also be considered a relevant comparator.* Where do you consider certolizumab pegol will fit into the existing NICE pathway for psoriasis? *Novartis: NICE has already approved multiple biologic therapies for plaque psoriasis[14-19] including newer agents, such as secukinumab,[14] which offer greater efficacy than subcutaneously administered TNF-alpha inhibitors.[20] Therefore we would expect certolizumab pegol to be positioned after the more effective biologics recommended by NICE.* NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. *Novartis: No comment.* Do you consider certolizumab pegol to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met? *Novartis: Since NICE has already approved multiple TNF-alpha inhibitors for plaque psoriasis[15,16,19] in addition to newer agents, such as secukinumab,[14]*	action required. NICE acknowledges that there are varying definitions of disease severity in psoriasis. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation. No action required. Infliximab is recommended for very severe psoriasis and has been excluded from the comparators. No action required.

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		which offer greater efficacy than subcutaneously administered TNF-alpha inhibitors,[20] , we do not consider certolizumab pegol will constitute a "step-change" in management of the condition Do you consider that the use of certolizumab pegol can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? *Novartis: No comment.* Do you consider that there will be any barriers to adoption of this technology into practice? *Novartis: No comment.* NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. *Novartis: We consider that the STA process is the appropriate route for this appraisal.* Would it be appropriate to use the cost comparison methodology for this topic? *Novartis: No comment.* Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators? *Novartis: No comment.* Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant? *Novartis: We note that the primary endpoints of the Phase III studies for certolizumab pegol include PASI 75 whilst PASI 90 was included as a secondary endpoint.[1-3] PASI 90 is increasingly recognised as the best*	Comment noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		evidence of efficacy[22] and a 'critical' outcome given its importance to people with psoriasis and should therefore be the main outcome goal for treatment.[23] Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year? *Novartis: The CLEAR study[24] was not available during the appraisal of secukinumab in plaque psoriasis (TA350). In this head-to-head, double-blind study, secukinumab demonstrated sustained superior efficacy in comparison with ustekinumab in clearing skin through to week 52, greater improvement in quality of life, and a favourable and comparable safety profile.* **References** 1. NCT02346240; https://clinicaltrials.gov/ct2/show/NCT02346240. Last accessed 29th September 2017. 2. NCT02326272; https://clinicaltrials.gov/ct2/show/NCT02326272. Last accessed 29th September 2017. 3. NCT02326298; https://clinicaltrials.gov/ct2/show/NCT02326298. Last accessed 29th September 2017. 14. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA350). Secukinumab for treating moderate to severe plaque psoriasis (2015). Available at https://www.nice.org.uk/guidance/ta350. Last accessed 29th September 2017. 15. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA146). Adalimumab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta146. Last accessed 29th September 2017.	Comments noted. Minimal clinically important differences for outcomes will be considered within the appraisal. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		16. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA103). Etanercept and efalizumab for the treatment of adults with psoriasis (2006). Available at https://www.nice.org.uk/guidance/ta103. Last accessed 29th September 2017. 17. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA180). Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009). Available at https://www.nice.org.uk/guidance/ta180. Last accessed 29th September 2017. 18. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA442). Ixekizumab for treating moderate to severe plaque psoriasis (2017). Available at https://www.nice.org.uk/guidance/ta442. Last accessed 29th September 2017. 19. National Institute for Health and Care Excellence (NICE). Technology Appraisal Guidance (TA134). Infliximab for the treatment of adults with psoriasis (2008). Available at https://www.nice.org.uk/guidance/ta134. Last accessed 13th October 2017. 20. Loos, A. M., et al. "COMPARATIVE EFFECTIVENESS OF TARGETED IMMUNOMODULATORS FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS." VALUE IN HEALTH. Vol. 20. No. 5. 360 PARK AVE SOUTH, NEW YORK, NY 10010-1710 USA: ELSEVIER SCIENCE INC, 2017. 22. Committee for Medicinal Products for Human Use. "Guideline on clinical investigation of medicinal products indicated for the treatment of psoriasis." London: European Medicines Agency (2004). Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003329.pdf. Last accessed 29th September 2017.	

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		23. Smith, C. H., et al. "British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017." British Journal of Dermatology (2017). 24. Blauvelt, Andrew, et al. "Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate-to-severe plaque psoriasis up to 1 year: Results from the CLEARs study." Journal of the American Academy of Dermatology 76.1 (2017): 60-69.	
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	None	Comment noted. No action required.
	UCB	*Are the subgroups suggested in 'other considerations' appropriate?* - Yes. *Where do you consider certolizumab pegol will fit into the existing NICE pathway for psoriasis?* We would expect certolizumab pegol to be positioned in line with other biologics reimbursed for treating moderate to severe psoriasis.	Comments noted. No action required.
Additional comments on the draft scope	AbbVie	Under the "Related NICE recommendations and NICE pathways" section we note that "Dimethyl fumarate for treating moderate to severe plaque psoriasis. NICE technology appraisal guidance [ID776]" has a publication date of 6th September 2017	Comment noted. The scope has been updated to reflect the published NICE guidance on dimethyl fumarate for treating moderate to severe plaque psoriasis.
	Eli Lilly and Company	We do not consider certolizumab pegol to represent a step-change in the treatment of moderate to severe psoriasis and we believe that it should be	Comments noted. The appraisal committee will

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		positioned as an alternative to biological treatments currently recommended by NICE. In order to be positioned earlier in the treatment pathway in plaque psoriasis that cannot be controlled with topical treatments, certolizumab pegol would need to be assessed as cost-effective versus phototherapy and non-biological systemic therapies based on an appropriate data package that includes head-to-head trial data with these treatments. As there are three proposed technology appraisals pending for other biologic therapies (guselkumab, brodalumab and tildrakizumab) in the treatment of moderate to severe psoriasis, a multiple technology appraisal may be appropriate to assess certolizumab pegol and these technologies. Appraisals relating to psoriatic arthritis, rheumatoid arthritis and axial spondyloarthritis are listed as 'Related Technology Appraisals' for only some technologies that have also been appraised in psoriasis. Not all technologies that have been appraised in both psoriasis and another indication have been listed (e.g. ustekinumab in psoriatic arthritis). We suggest that this section should only list appraisals in psoriasis.	discuss the potentially innovative nature of this technology. No action required. The 'Related technology appraisals' include "Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed" because it includes the technology to be appraised. No action required.
	Novartis Pharmaceuticals UK Ltd	In "Related NICE recommendations and NICE Pathways"; • The appraisal of dimethyl fumarate in plaque psoriasis was published on 6th September 2017, so this should be moved from being an "appraisal in development" to a "related technology appraisal"	Comment noted. The scope has been updated to reflect the published NICE guidance on dimethyl fumarate for treating

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		• A surveillance review of NICE clinical guideline 153; 'Psoriasis: assessment and management', was carried out in 2017 and the guideline was updated in September 2017.	moderate to severe plaque psoriasis.
	Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	None	Comment noted. No action required.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

British Association of Dermatologists
Department of Health