

**SPECIALISED COMMISSIONING – RESPONSE TO AMENDMENTS REQUESTED TO EVIDENCE REVIEW DURING ENGAGEMENT OR CONSULTATION**

<b>URN</b>	1921
<b>POLICY TITLE</b>	Clinical Commissioning Policy Statement Abatacept for treatment of severe treatment-resistant morphea (localised scleroderma) (adults and children 2 years and over)
<b>CRG:</b>	Specialised Rheumatology
<b>NPOC:</b>	Internal Medicine
<b>Date</b>	07/10/2020

<b>Description of comments during consultation (If studies have been suggested please provide a list of references)</b>	<p>10 references were suggested during consultation:</p> <ol style="list-style-type: none"> <li>Asano Y, Jinnin M, Kawaguchi Y, Kuwana M, Goto D, Sato S, Takehara K, Hatano M, Fujimoto M, Mugii N, Ihn H. Diagnostic criteria, severity classification and guidelines of systemic sclerosis. <a href="#">J Dermatol. 2018 Jun;45(6):633-691.</a></li> <li>Constantin T, Foeldvari I, Pain CE, Pálincás A, Höger P, Moll M, Nemkova D, Weibel L, Laczkovszki M, Clements P, Torok KS. Development of minimum standards of care for juvenile localized scleroderma. <a href="#">Eur J Pediatr. 2018 Jul;177(7):961-977.</a></li> <li>Fett NM. Morphea: evidence-based recommendations for treatment. <a href="#">Indian J Dermatol Venereol Leprol. 2012 Mar-Apr;78(2):135-41.</a></li> <li>Knobler R, Moinzadeh P, Hunzelmann N, Kreuter A, Cozzio A, Mouthon L, Cutolo M, Rongioletti F, Denton CP, Rudnicka L, Frasin LA, Smith V, Gabrielli A, Aberer E, Bagot M, Bali G, Bouaziz J, Braae Olesen A, Foeldvari I, Frances C, Jalili A, Just U, Kähäri V, Kárpáti S, Kofoed K, Krasowska D, Olszewska M, Orteu C, Panelius J, Parodi A, Petit A, Quaglino P, Ranki A, Sanchez Schmidt JM, Seneschal J, Skrok A, Sticherling M, Sunderkötter C, Taieb A, Tanew A, Wolf P, Worm M, Wutte NJ, Krieg T. European Dermatology Forum S1-guideline on the diagnosis and treatment of sclerosing diseases of the skin, Part 1: localized scleroderma, systemic sclerosis and overlap</li> </ol>
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syndromes. [J Eur Acad Dermatol Venereol. 2017 Sep;31\(9\):1401-1424.](#)

5. Kreuter A, Krieg T, Worm M, Wenzel J, Gambichler T, Kuhn A, Aberer E, Scharffetter-Kochanek K, Hunzelmann N; Deutsche Dermatologische Gesellschaft. AWMF-Leitlinie Nr. 013/066. Diagnostik und Therapie der zirkumskripten Sklerodermie [AWMF Guideline no. 013/066. Diagnosis and therapy of circumscribed scleroderma]. [J Dtsch Dermatol Ges. 2009 Sep;7 Suppl 6:S1-14.](#)
6. Kreuter A, Krieg T, Worm M, Wenzel J, Moinzadeh P, Kuhn A, Aberer E, Scharffetter-Kochanek K, Horneff G, Reil E, Weberschock T, Hunzelmann N. German guidelines for the diagnosis and therapy of localized scleroderma. [J Dtsch Dermatol Ges. 2016 Feb;14\(2\):199-216.](#)
7. Kalampokis I, Yi BY, Smidt AC. Abatacept in the treatment of localized scleroderma: A pediatric case series and systematic literature review. [Semin Arthritis Rheum. 2020 Aug;50\(4\):645-656](#)
8. Li SC, Torok KS, Pope E, Dedeoglu F, Hong S, Jacobe HT, Rabinovich CE, Laxer RM, Higgins GC, Ferguson PJ, Lasky A, Baszis K, Becker M, Campillo S, Cartwright V, Cidon M, Inman CJ, Jerath R, O'Neil KM, Vora S, Zeff A, Wallace CA, Ilowite NT, Fuhlbrigge RC; Childhood Arthritis and Rheumatology Research Alliance (CARRA) Localized Scleroderma Workgroup. Development of consensus treatment plans for juvenile localized scleroderma: a roadmap toward comparative effectiveness studies in juvenile localized scleroderma. [Arthritis Care Res \(Hoboken\). 2012 Aug;64\(8\):1175-85.](#)
9. Lythgoe H, Almeida B, Bennett J, Bhat C, Bilkhu A, Brennan M, Deepak S, Dawson P, Eleftheriou D, Harrison K, Hawley D, Heaf E, Leone V, Long E, Maltby S, McErlane F, Rafiq N, Ramanan AV, Riley P, Rangaraj S, Varnier G, Wilkinson N, Pain CE. Multi-centre national audit of juvenile localised scleroderma: describing current UK practice in disease assessment and management. [Pediatr Rheumatol Online J. 2018 Dec 18;16\(1\):80.](#)

	<p>10. Zulian F, Culpo R, Sperotto F, Anton J, Avcin T, Baildam EM, Boros C, Chaitow J, Constantin T, Kasapcopur O, Knupp Feitosa de Oliveira S, Pilkington CA, Russo R, Toplak N, van Royen A, Saad Magalhães C, Vastert SJ, Wulffraat NM, Foeldvari I. Consensus-based recommendations for the management of juvenile localised scleroderma. <a href="#">Ann Rheum Dis. 2019 Aug;78(8):1019-1024.</a></p>
<b>Action taken by Public Health lead</b>	<p>Full text copies of all papers were acquired and read in reference to the PICO details.</p>
<b>Outcome for studies suggested during consultation</b>	
<b>1. Evidence already identified during the evidence review</b>	<p>None</p>
<b>2. New evidence identified by stakeholders that does not fall within PICO and search methodology</b>	<p>1 Asano Y, Jinnin M, Kawaguchi Y, Kuwana M, Goto D, Sato S, Takehara K, Hatano M, Fujimoto M, Mugii N, Ihn H. Diagnostic criteria, severity classification and guidelines of systemic sclerosis. <a href="#">J Dermatol. 2018 Jun;45(6):633-691.</a></p> <p>2. Constantin T, Foeldvari I, Pain CE, Pálincás A, Höger P, Moll M, Nemkova D, Weibel L, Laczkovszki M, Clements P, Torok KS. Development of minimum standards of care for juvenile localized scleroderma. <a href="#">Eur J Pediatr. 2018 Jul;177(7):961-977.</a></p> <p>3. Fett NM. Morphea: evidence-based recommendations for treatment. <a href="#">Indian J Dermatol Venereol Leprol. 2012 Mar-Apr;78(2):135-41.</a></p> <p>4. Knobler R, Moinzadeh P, Hunzelmann N, Kreuter A, Cozzio A, Mouthon L, Cutolo M, Rongioletti F, Denton CP, Rudnicka L, Frasin LA, Smith V, Gabrielli A, Aberer E, Bagot M, Bali G, Bouaziz J, Braae Olesen A, Foeldvari I, Frances C, Jalili A, Just U, Kähäri V, Kárpáti S, Kofoed K, Krasowska D, Olszewska M, Orteu C, Panelius J, Parodi A, Petit A, Quaglino P, Ranki A, Sanchez Schmidt JM, Seneschal J, Skrok A, Sticherling M, Sunderkötter C, Taieb A, Tanew A, Wolf P, Worm M, Wutte NJ, Krieg T. European Dermatology Forum S1-guideline on the diagnosis and treatment of</p>

sclerosing diseases of the skin, Part 1: localized scleroderma, systemic sclerosis and overlap syndromes. [J Eur Acad Dermatol Venereol. 2017 Sep;31\(9\):1401-1424..](#)

5. Kreuter A, Krieg T, Worm M, Wenzel J, Gambichler T, Kuhn A, Aberer E, Scharffetter-Kochanek K, Hunzelmann N; Deutsche Dermatologische Gesellschaft. AWMF-Leitlinie Nr. 013/066. Diagnostik und Therapie der zirkumskripten Sklerodermie [AWMF Guideline no. 013/066. Diagnosis and therapy of circumscribed scleroderma]. [J Dtsch Dermatol Ges. 2009 Sep;7 Suppl 6:S1-14.](#)

6. Kreuter A, Krieg T, Worm M, Wenzel J, Moinzadeh P, Kuhn A, Aberer E, Scharffetter-Kochanek K, Horneff G, Reil E, Weberschock T, Hunzelmann N. German guidelines for the diagnosis and therapy of localized scleroderma. [J Dtsch Dermatol Ges. 2016 Feb;14\(2\):199-216.](#)

8. Li SC, Torok KS, Pope E, Dedeoglu F, Hong S, Jacobe HT, Rabinovich CE, Laxer RM, Higgins GC, Ferguson PJ, Lasky A, Baszis K, Becker M, Campillo S, Cartwright V, Cidon M, Inman CJ, Jerath R, O'Neil KM, Vora S, Zeft A, Wallace CA, Ilowite NT, Fuhlbrigge RC; Childhood Arthritis and Rheumatology Research Alliance (CARRA) Localized Scleroderma Workgroup. Development of consensus treatment plans for juvenile localized scleroderma: a roadmap toward comparative effectiveness studies in juvenile localized scleroderma. [Arthritis Care Res \(Hoboken\). 2012 Aug;64\(8\):1175-85.](#)

9. Lythgoe H, Almeida B, Bennett J, Bhat C, Bilkhu A, Brennan M, Deepak S, Dawson P, Eleftheriou D, Harrison K, Hawley D, Heaf E, Leone V, Long E, Maltby S, McErlane F, Rafiq N, Ramanan AV, Riley P, Rangaraj S, Varnier G, Wilkinson N, Pain CE. Multi-centre national audit of juvenile localised scleroderma: describing current UK practice in disease assessment and management. [Pediatr Rheumatol Online J. 2018 Dec 18;16\(1\):80.](#)

10. Zulian F, Culpo R, Sperotto F, Anton J, Avcin T, Baildam EM, Boros C, Chaitow J, Constantin T, Kasapcopur O, Knupp Feitosa de Oliveira S,

	<p>Pilkington CA, Russo R, Toplak N, van Royen A, Saad Magalhães C, Vastert SJ, Wulffraat NM, Foeldvari I. Consensus-based recommendations for the management of juvenile localised scleroderma. <a href="#">Ann Rheum Dis. 2019 Aug;78(8):1019-1024.</a></p>
<p><b>3.New evidence identified by stakeholders that falls within PICO and search methodology but does not materially affect the conclusions of the existing evidence review</b></p>	<p>7. Kalampokis I, Yi BY, Smidt AC. Abatacept in the treatment of localized scleroderma: A pediatric case series and systematic literature review. <a href="#">Semin Arthritis Rheum. 2020 Aug;50(4):645-656</a></p> <p>This paper was discussed with the Policy Working Group and informed the statement on treatment in children.</p>
<p><b>4.New evidence identified by stakeholders that falls within PICO and search methodology, that does materially affect the conclusions of the existing evidence review. Updated evidence review to be undertaken (agreed with CET)</b></p>	<p>None</p>