South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference:	**054**
Intervention:	**9-valent papillomavirus vaccine (Gardasil 9®) for the treatment of recalcitrant anogenital warts in adults** (Gardasil is a vaccine comprising protein from Type 6, 11, 16, 18, 31, 33, 45, 52, 58 human papillomavirus)
Date of Decision	**October 2016. Updated in October 2021**
Date of Issue:	**April 2017. Re-issued November 2021 following change in formulation.**
Recommendation:	**RED – suitable for prescribing, supply and administration through hospital/specialist sexual health clinics only**
Further Information:	9-valent human papillomavirus (HPV) vaccine (Gardasil 9®) is accepted for use in SEL for the **treatment** of recalcitrant anogenital warts in both HIV-negative and HIV-positive adults in line with South East London treatment guidance for the management of anogenital warts in men and women. In line with the SEL guidance the following criteria must be met: • In people with multiple external warts, Gardasil 9® is a 3rd line treatment option after both imiquimod and podophyllotoxin have been tried: – In people with one external wart, Gardasil 9® is a 4th line treatment option after cryotherapy, imiquimod and podophyllotoxin have all been tried. – Gardasil 9® is a 3rd line treatment option, after both cryotherapy and imiquimod for peri-anal warts, keratinised or bulky warts (>4cm), and urethral meatal warts in men. – Use of quadrivalent HPV vaccine requires multidisciplinary team (MDT) approval at individual trust level. The MDT must include **at least** two sexual health consultants. • A total of **3 doses** of Gardasil 9® vaccine will be administered at 0, 2 and 6 months. • Use of Gardasil 9® for the treatment of anogenital warts is unlicensed* and outside national UK recommendations for use of the vaccine. • Further information regarding the use of Gardasil 9® in line with the official national UK immunisation programme can be accessed here. • Local anecdotal evidence suggests use of the HPV vaccine could lead to a reduction in the need for surgery and fewer follow up appointments. Addition to the formulary will also remove the need for Individual Funding Request (IFR) applications. • The six local authorities in SEL (as the commissioners of sexual health services) have confirmed their support for the inclusion of HPV vaccine in the formulary for treatment of recalcitrant anogenital warts in adults. • In December 2019 Trusts reported data back to the Committee as part of the original approval. Only one Trust was implementing the use of the HPV vaccine in this setting. Data provided by the Trust indicates a reduction in the need for cryotherapy in patients treated with the vaccine. • Funding for use of Gardasil 9® in this setting will need to be confirmed at individual Trust level. *Gardasil 9® is licensed in the UK for use from the age of 9 years for the **prevention** of: (i) premalignant genital lesions (cervical, vulvar and vaginal), premalignant anal lesions, cervical cancers and anal cancers causally related to certain oncogenic Human Papillomavirus (HPV) types (ii) genital warts (condyloma acuminata) causally related to specific HPV types.
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	• It is estimated there will be approximately 47 patients per year eligible for treatment across SEL. • A 3 dose course of Gardasil 9® costs £378 (including VAT). • Based on this the total cost impact in SEL would be ~£935 per 100,000 population, assuming each patient received the maximum 3 dose course.
Usage Monitoring & Impact Assessment	Acute Trusts/sexual health clinics: • Monitor use and submit usage data and audit reports (against this recommendation and the SEL treatment guidance) upon request to the SEL IMOC.
	SEL CCG Borough Medicines Optimisation Teams: • Monitor ePACT2 data • Monitor exception reports from GPs if inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	**References (from evidence review)** 1. NICE Clinical Knowledge Summaries: Warts – anogenital, Last revised November 2012. Available at: http://cks.nice.org.uk/warts-anogenital#!topicsummary 2. Coles, V. et al. The costs of managing genital warts in the UK by devolved nation: England, Scotland, Wales and Northern Ireland. International Journal of STD & AIDS. 2016; 27(1): 51-7. 3. BASHH. UK National Guidelines on the Management of Anogenital Warts 2015. Accessed via: http://www.bashh.org/BASHH/Guidelines/Guidelines/BASHH/Guidelines/Guidelines.aspx 4. Sanofi Pasteur Gardasil Summary of Product Characteristics. Last updated 04/05/2016. Available at: http://www.medicines.org.uk/emc/medicine/19016/SPC/GARDASIL/ 5. Daayana, S. et al. Phase II trial of imiquimod and HPV therapeutic vaccination in patients with vulval intraepithelial neoplasia. British Journal of Cancer. 2010; 102: 1129-36. 6. Park, I. et al. Human Papillomavirus and genital warts: a review of the evidcence for the 2015 Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines. Clinical Infectious Diseases. 2015; 61(S8): S849-55. 7. Joura, E. et al. Effect of the human papillomavirus (HPV) quadrivalent vaccine in a subgroup of women with cervical and vulvar disease: retrospective pooled analysis of trial data. British Medical Journal. 2012; 344: e1401. 8. Hildesheim, A. et al. Effect of human papillomavirus 16/18 L1 viruslike particle vaccine among young women with pre-existing infection. JAMA. 2007; 298(7): 743-53. 9. Venugopal, S. and Murell, D. Recalcitrant cutaneous warts treated with recombinant quadrivalent human papillomavirus vaccine (Types 6, 11, 16, and 18) in a developmentally delayed, 31 year old white man. Archives of Dermatology. 2010; 146(5): 475-7. 10. Lee, H. et al. Condyloma accuminatum treated with recombinant quadrivalent human papillomavirus vaccine (types 6, 11, 16, 18). J Am Acad Dermatol. 2011; 64(6): e130-2. 11. Daniel, B. and Murrell, D. Complete resolution of chronic multiple verruca vulgaris treated with quadrivalent human papillomavirus vaccine. JAMA Dermatology. 2013; 149(3): 370-2. 12. Cid-Arregu, A. Therapeutic vaccines against human papillomavirus and cervical cancer. Open Virology Journal. 2009; 3: 67-83. 13. Summary of Product Characteristics. Gardasil 9 suspension for injection 2021. Date last accessed: 05/11/2021. Date of revision of the text: 01/01/2021. https://www.medicines.org.uk/emc/product/7330/smpc

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.

b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS.