South East London Area Prescribing Committee
Formulary recommendation

Reference:	**054**
Intervention:	**Quadrivalent human papillomavirus vaccine (Gardasil®) for the treatment of recalcitrant anogenital warts in adults** (Gardasil is a vaccine comprising protein from Type 6, 11, 16 and 18 human papillomavirus)
Date of Decision	**October 2016**
Date of Issue:	**April 2017**
Recommendation:	**RED – suitable for prescribing, supply and administration through hospital/specialist sexual health clinics only**
Further Information:	Gardasil 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 is a 3rd line treatment option after both imiquimod and podophyllotoxin have been tried – In people with one external wart, Gardasil is a 4th line treatment option after cryotherapy, imiquimod and podophyllotoxin have all been tried. – Gardasil 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 vaccine will be administered at 0, 2 and 6 months. • Use of Gardasil for the treatment of anogenital warts is unlicensed* and outside national UK recommendations for use of the vaccine. • The official national UK immunisation programme only supports use of Gardasil in girls aged 12 to 13 years for the prevention of cervical cancer. • The APC acknowledged that there is a lack of evidence in this area. However, local anecdotal evidence suggests use of Gardasil 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 Gardasil in the formulary for treatment of recalcitrant anogenital warts in adults. • Trusts will collate and report data back to the Committee in 12 months (April 2018); to be coordinated by the Trust submitting the formulary application) outlining: – The total numbers of patients Gardasil has been used in per SEL borough. – Whether use is in line with this recommendation and the treatment guidance – Patient related outcomes, including overall response to treatment and adverse effects – Impact on service activity (such as the need for surgery and follow up appointments). • Funding for use of Gardasil in this setting will need to be confirmed at individual Trust level. *Gardasil 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 75 patients per year eligible for treatment across SEL. • A 3 dose course of Gardasil costs £311.40 (including VAT) • Based on this the total cost impact in SEL would be ~£24,000, assuming each patient received the maximum 3 dose course.
Usage Monitoring & Impact Assessment	Acute Trusts/sexual health clinics: • Monitor and audit usage of Gardasil. Collate outcome data as agreed and outlined in the "Further Information" section of this recommendation and report back to the Committee in April 2018.
	CCGs: • Monitor ePACT 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.

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.

b) This Area Prescribing Committee 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.**