High-Grade Cervical Intraepithelial Neoplasia in the United States and Europe

FACT SHEET

Treatment

The standard of care for women identified with cervical intraepithelial neoplasia grade 2 or 3 (CIN2/3) is surgical excision, the most common form being loop electrosurgical excision procedure (LEEP):

- LEEP involves the use of a heated wire loop to cut abnormal cells from the surface of the cervix
- LEEP is initially effective at removing precancerous lesions but does not treat the causative human papillomavirus (HPV) infection, leading to recurrence of lesions in 10% to 16% of women
- No treatments are currently available for women diagnosed with CIN1 or the underlying HPV infection
  - Patients with CIN1 undergo “watchful waiting” to monitor the status of their lesions

Risks of LEEP

- Recurrence
- Preterm birth
- Infertility
- Menstruation problems
- Heavy bleeding
- Cramping
- Black discharge

Unmet need

Inovio Pharmaceuticals’ goal is to provide women with a non-surgical option for CIN2/3 treatment. We want to give women the option to choose a less invasive procedure that not only treats their cervical dysplasia but also clears the underlying HPV infection. We strive to provide women with a treatment option that does not cause risk to their reproductive health.

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About cervical dysplasia

CIN, also known as cervical dysplasia, is classified as premalignant changes in cervical cells that, if left untreated, can advance to cervical cancer. CIN most often occurs in younger women (aged 25 to 35 years) and is divided into three progressive stages (ie, CIN1, CIN2, and CIN3). CIN2/3 is considered high grade, as these lesions have the highest risk of becoming cancerous.

The cause of cervical dysplasia is persistent infection with one or more high-risk genotypes of HPV. HPV, a sexually transmitted infection, infects approximately 12% of women who do not yet have CIN worldwide. High-risk HPV genotypes are those types with high potential to cause cancer. HPV 16 and HPV 18 are the two genotypes most likely to cause high-grade CIN. These two genotypes are estimated to cause approximately 70% of all cervical cancers in the United States and worldwide.

Although effective prophylactic vaccines for HPV have been available for several years, only 40% of eligible adolescent females (aged 13 to 17 years) in the United States received all three doses of the regimen in 2014. Furthermore, despite well-known HPV preventive measures (eg, use of condoms during sexual relations, limiting the number of sexual partners), these behavioral measures are not practiced universally. Therefore, it is expected that high-risk HPV infections, the resulting high-grade CIN incidence, and the burden of cervical cancer will continue to be a substantial public health problem in the United States and worldwide for years to come.

References

8. 20% to 40% spontaneous regression of CIN2/3 to CIN1 or normal at 9 to 12 months post-diagnosis.
9. 43% progression from HPV 16/18 CIN3 to cervical carcinoma in situ at 1 year if left untreated.