Public Statement:

There are intrauterine devices that have slow release of progesterone (Progestasert) or levonorgestrel (a synthetic progestational hormone - Mirena) that are FDA approved for contraception. The devices may remain in place for up to 5 years.

Medical Policy Statement:

1) These devices are covered for contraception under the contraception benefit.

2) Mirena is covered under the medical benefit for treatment of dysfunctional uterine bleeding, menometrorrhagia, or metrorrhagia.

Background:

Lethaby et al: “Progestosterone or progestogen-releasing intrauterine systems have not been compared to placebo or no treatment. Progestasert has been compared to a number of different medical therapies in one small study but no conclusions can be made about its effectiveness. The levonorgestrel-releasing intrauterine device has been compared to oral cyclical norethisterone administered on days 5 to 26 of the menstrual cycle in one trial and was significantly more effective although there was a large reduction in loss from baseline in both groups. Some short term side effects were more common in the LNG IUS group but a significantly greater proportion of women in this group were satisfied and willing to continue with their treatment. The levonorgestrel-releasing intrauterine device (LNG IUS) has been compared to oral cyclical norethisterone (NET) administered on days 5 to 26 of the menstrual cycle in one
trial and was significantly more effective although there was a large reduction in loss from baseline in both groups. Some short term side effects were more common in the LNG IUS group but a significantly greater proportion of women in this group were satisfied and willing to continue with their treatment. In one trial of women awaiting hysterectomy, where the LNG IUS was compared with a control group taking their existing medical therapy, a higher proportion of the women in the intrauterine device group cancelled their planned surgery after six months of treatment. The LNG IUS has been compared to an endometrial ablation: either transcervical resection of the endometrium (TCRE) (two trials) or balloon ablation (three trials). There was a significantly greater mean reduction in menstrual bleeding in one trial in those undergoing balloon ablation (WMD -45.2 units, 95% CI -56.9 to -33.5), a lower score on the pictorial blood loss chart (PBAC) (WMD 33.2 units, 95% CI 27.2 to 39.2) and higher rates of successful treatment in 3 trials including both balloon and TCRE (OR 0.28, 95% CI 0.14 to 0.58) but the rates of satisfaction with treatment was were similar. There was no conclusive evidence of changes in quality of life between groups but women with the LNG IUS had a greater incidence of progestogenic side effects within one year. The LNG IUS has been compared to hysterectomy in one trial. There was no evidence of a change in quality of life scores but the LNG IUS treatment had lower costs than with hysterectomy, both at one and five-years follow up.

They concluded "The levonorgestrel-releasing intrauterine device (LNG IUS) is more effective than cyclical norethisterone (for 21 days) as a treatment for heavy menstrual bleeding. Women with an LNG IUS are more satisfied and willing to continue with treatment but experience more side effects, such as intermenstrual bleeding and breast tenderness. The LNG IUS results in a smaller mean reduction in menstrual blood loss (as assessed by the PBAC chart) than endometrial ablation but there is no evidence of a difference in the rate of satisfaction with treatment. Women with an LNG IUS experience more progestogenic side effects compared to women having TCRE (transcervical resection of endometrium) for treatment of their heavy menstrual bleeding but there is no evidence of a difference in their perceived quality of life. The LNG IUS treatment costs less than hysterectomy but there is no evidence of a difference in quality of life measures between these groups. There are no data available from randomised controlled trials comparing progesterone-releasing intrauterine systems to either placebo or other commonly used medical therapies for heavy menstrual bleeding."

Petta and others reported: “Eighty-two women, 18 to 40 years of age (mean 30 years), with endometriosis, dysmenorrhoea and/or CPP, were randomized using a computer-generated system of sealed envelopes into either LNG-IUS (n = 39) or GnRH analogue (n = 43) treatment groups at three university centres. Daily scores of endometriosis-associated CPP were evaluated using the Visual Analogue Scale (VAS), daily bleeding score was calculated from bleeding calendars, and improvement in quality of life was evaluated using the Psychological General Well-Being Index Questionnaire (PGWBI). The pain score diary was based on the VAS in which women recorded the occurrence and intensity of pain on a daily basis. A monthly score was calculated from the result of the sum of the daily scores divided by the number of days in each observation period.
RESULTS: CPP decreased significantly from the first month throughout the six months of therapy with both forms of treatment and there was no difference between the groups (P > 0.999). In both treatment groups, women with stage III and IV endometriosis showed a more rapid improvement in the VAS pain score than women with stage I and II of the disease (P < 0.002). LNG-IUS users had a higher bleeding score than GnRH-analogue users at all time points of observation with 34% and 71% of patients in the LNG-IUS and GnRH-analogue groups, respectively, reporting no bleeding during the first treatment month, and 70% and 98% reporting no bleeding during the sixth month. No difference was observed between groups with reference to improvement in quality of life."

“CONCLUSIONS: "Both, the LNG-IUS and the GnRH-analogue were effective in the treatment of CPP-associated endometriosis, although no differences were observed between the two treatments. Among the additional advantages of the LNG-IUS is the fact that it does not provoke hypoestrogenism and that it requires only one medical intervention for its introduction every 5 years. This device could therefore become the treatment of choice for CPP-associated endometriosis in women who do not wish to conceive.”

References:


Lockhat FB, Emembolu JO, Konie JC.(2005) The efficacy, side-effects and continuation rates in women with symptomatic endometriosis undergoing treatment with an intra-


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

Last modified by: Date: