NICE Medicines Update:

Nice Guidance	Background	Cost Implications	Points to consider	Response of HRW CCG
TA 547: Tofacitinib for moderately to severely active ulcerative colitis Tofacitinib is recommended, within its marketing authorisation, as an option for treating moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated or the disease has responded inadequately or lost response to treatment. It is recommended only if the company provides tofacitinib with the discount agreed in the commercial arrangement.	Clinical trial evidence shows that tofacitinib is more effective than placebo for treating moderately to severely active ulcerative colitis. An indirect comparison suggests that for people who have not had a TNF-alpha inhibitor, tofacitinib is more effective than adalimumab and golimumab as maintenance treatment. For people who have had a TNF-alpha inhibitor, tofacitinib is more effective than adalimumab as induction treatment. No other statistically significant differences between tofacitinib and biological therapies were identified. Based on the health-related benefits and costs compared with conventional therapy and biologicals, tofacitinib is recommended as a cost-effective treatment for moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to, or who cannot tolerate, conventional or biological therapy.	The financial implication is likely to be £6,500 in year 1 increasing to £22,579 by year 5.	This is already available on formulary as previously approved by NICE for management of rheumatoid arthritis.	**Approve in line with NICE guidance.**
TA 556: Darvadstrocel for treating complex perianal fistulas in Crohn's disease Darvadstrocel is **not recommended**, within its marketing authorisation, for previously treated complex perianal fistulas in adults with non-active or mildly active luminal Crohn's disease.	In a single clinical trial comparing remission rates for darvadstrocel and placebo, only an additional 14% of people showed a beneficial effect from darvadstrocel over and above placebo. Reliable follow-up results are only available for up to 1 year during which time more than 50% of patients who had remission subsequently relapsed in both the darvadstrocel and placebo arms, so it is unclear how long the treatment benefit will last. The additional evidence submitted after consultation did not clarify the uncertainties around long-term benefits of darvadstrocel. The committee considered that further research in this area would be beneficial. The cost-effectiveness estimates are therefore highly uncertain and the committee was unable to decide on the most plausible cost-effectiveness estimate. Because of this, darvadstrocel cannot be recommended for routine commissioning for treating complex perianal, fistulas in people with Crohn's disease.	There are no additional financial implications because NICE does not recommend this treatment.	This is to be classified on the local formulary as BLACK and therefore NOT supported for prescribing in either primary and secondary care	To adhere to the NICE TA and support the CCG commissioning position **not to recommend its use.**