Appendix 4: Criteria for clinical risk assessment of off-label medicines or specials

Established Practice	Low Risk	High Risk
Established generally e.g. BNF, BNF for Children, nationally recognised guidelines e.g. NICE, SIGN, BAP guidelines,	• Established use in speciality e.g. Specialist published guidelines • Phase III / IV clinical trial data published in established Journals	Phase I or II clinical trials or case reports, abstracts of phase III/IV
Few significant side effects		• Teratogenic • Carcinogenic • Cytotoxic • Biological Agent
• Oral / external • Subcutaneous / respiratory / nasal	Established intravenous practice	• Intrathecal • Epidural • All other intravenous use or installation into cavity or bone

Any off-label medicine fulfilling any of the criteria in the high risk column automatically requires an **Unlicensed/High Risk Off-label Medicine form** to be completed and sent on for approval as outlined in the form and the **ULM Approval Flow Chart**.

Please note – there is an element of subjectivity in assigning clinical risk category. The above table provides guidance only and should not be considered as an exhaustive list. Discussion should take place with clinical peers, Medicines Information and clinical pharmacists as required to assign the risk.