

MTF Formulary Management for the Gastrointestinal – 1 Drug Class
Oral Aminosalicylates (5-ASA) Subclass
 Defense Health Agency Pharmacy Operations Division

Bottom Line:

- Lialda is the preferred 5-ASA oral agent for inflammatory bowel disease (IBD), and is now BCF.
- Asacol is no longer commercially available; it has been replaced with a new phthalate-free formulation, Delzicol.
- Asacol HD and Pentasa are now non-formulary.
- Drug selection depends on disease location, severity and patient tolerance. Tailor therapy to the individual patient.

Uniform Formulary Decision: The Director, DHA approved recommendations from the February 2014 DoD P&T Committee meeting. The BCF selection and non-formulary products became effective August 6, 2014.

Uniform Formulary (UF) Agents		Non-Formulary Agents
GI-1 agents on BCF MTFs <u>must</u> have on formulary	GI-1 agents not on BCF MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
Mesalamine multimatrix (Lialda) Sulfasalazine (Azulfidine, generics)	Balsalazide 750 mg (Colazal; generics) Olsalazine (Dipentum) Mesalamine delayed release tabs (Delzicol) Mesalamine capsules (Apriso)	Mesalamine high dose (Asacol HD) Mesalamine (Pentasa) Balsalazide 1100 mg (Giazo)

- Maximize use of Lialda for induction and maintenance of remission in active ulcerative colitis (UC); efficacy has been firmly established in several clinical trials. Sulfasalazine is also a 1st line treatment.
- Asacol has been withdrawn from the market in response to FDA’s guidance on avoiding phthalates in pharmaceuticals. Asacol’s replacement is the phthalate-free formulation, Delzicol. No clinical studies were conducted with Delzicol; approval was based on established bioequivalence to Asacol.
- In the U.S., there are no direct comparative trials comparing the newer formulations of mesalamine- Delzicol, Asacol HD, Lialda and Apriso.
- The 5-ASA formulations employ different mechanisms to prevent dissolution and drug absorption in the upper GI tract, which ensures drug is released in areas where the bowel is inflamed (the terminal ileum and colon). Differences in the oral release mechanisms do not confer clinically relevant differences in efficacy.
- The 5-ASA safety profiles are similar; however, sulfasalazine and olsalazine are less well-tolerated.
- Giazo is a new balsalazide product with limited clinical utility, as it is only approved for use in men with mild to moderate UC. Women treated with Giazo reported more adverse effects in clinical trials than men.
- Lialda and Apriso are the only products administered once daily. There is no difference in efficacy or safety between once daily 5-ASA and conventional (twice/thrice daily) dosing.
- American College of Gastroenterology Guidelines no longer recommend 5-ASAs for treating mild to moderate Crohn’s Disease. Budesonide and conventional steroids are preferred for this indication.

References

- DoD P&T Committee minutes are available at http://pec.ha.osd.mil/pt_minutes.php?submenuheader=5
- Current/future drug classes under review by the DoD P&T Committee: http://pec.ha.osd.mil/PT_Committee.php?submenuheader=4
- TRICARE formulary search tool http://pec.ha.osd.mil/formulary_search.php?submenuheader=1
- Prior Authorization/Medical Necessity forms can be downloaded at http://pec.ha.osd.mil/forms_criteria.php?submenuheader=1
- Point Of Contact: For more information usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil

5-ASA MTF Price Comparison		
Drug	MTF Weighted Average Cost	
Basic Core Formulary		MTF Cost
Sulfasalazine	\$	“Most Cost-Effective”
Lialda	\$	“Most Cost-Effective”
UF 5 ASAs		
Balsalazide	\$\$	“Less Cost-Effective”
Dipentum	\$\$	“Less Cost-Effective”
Apriso	\$\$\$	“Less Cost-Effective”
Delzicol	\$\$\$	“Less Cost-Effective”
NF 5 ASAs		
Asacol HD	\$\$\$\$	“Least Cost-Effective”
Pentasa	\$\$\$\$	“Least Cost-Effective”
Giazo	\$\$\$\$\$	“Least Cost-Effective”