

Supplementary

Supplement, Table 1 Biological drugs approved for the treatment of IBDs in Italy

Biological drugs approved for IBDs in Italy	Therapeutic class	Indications for use approved for IBDs	Other indications for use approved in Italy
Infliximab	TNF-alpha inhibitors	<p><u>Adult Crohn's disease:</u></p> <ul style="list-style-type: none"> • treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies; • treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). <p><u>Paediatric Crohn's disease:</u> treatment of severe, active Crohn's disease, in children and adolescents aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. Infliximab has been studied only in combination with conventional immunosuppressive therapy.</p> <p><u>Adult ulcerative colitis:</u> treatment of moderately to severely active ulcerative</p>	RA, PsA, AS, PsO

		<p>colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.</p> <p><u>Paediatric ulcerative colitis:</u> treatment of severely active ulcerative colitis, in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.</p>	
Adalimumab	TNF-alpha inhibitors	<p><u>Adult Crohn's disease:</u> treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies;</p> <p><u>Paediatric Crohn's disease:</u> treatment of moderately to severely active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies.</p>	RA, PsA, AS, JIA, PsO, Uv, HS

		<p><u>Adult ulcerative colitis:</u> treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies;</p> <p><u>Paediatric ulcerative colitis:</u> treatment of moderately to severely active ulcerative colitis in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.</p>	
Golimumab	TNF-alpha inhibitors	<p><u>Adult ulcerative colitis:</u> treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.</p>	RA, PsA, AS, JIA
Vedolizumab	Anti-integrins	<p><u>Adult Crohn's disease:</u> treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.</p>	-

		<p><u>Adult ulcerative colitis</u>: treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.</p>	
Ustekinumab	Interleukin inhibitors	<p><u>Adult Crohn's disease</u>: treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies.</p> <p><u>Adult ulcerative colitis</u>: treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.</p>	PsO, PsA

Abbreviations: IBDs= inflammatory bowel diseases; TNF= tumor necrosis factor; RA= Rheumatoid arthritis; PsA= Psoriatic arthritis; AS= Ankylosing spondylitis; PsO= Psoriasis; JIA= Juvenile idiopathic arthritis; Uv=Uveitis; HS= Hidradenitis suppurativa.

Supplement, Table 2 NDC of mesalazine with specific indication for use for UC, according to Italian SmPCs

Formulations	NDC
TABLETS 1200 MG	037734023 037734011
ENEMAS 2G	027357108 035358035 035356031 033081023 026416216
ENEMAS 2G/30ML	027308042
ENEMAS 2G/50ML	034462034 026416141 035386046 034295030
ENEMAS 4G	034836039 035358047 035356043 033081035 026416230
ENEMAS 4G/50ML	026416166 029050034
ENEMAS 4G/100ML	033529037 033760344 033256037 035386034 029480047 033292018 026416154 029050046
ENEMAS 4G/60ML	027308055 027357110

VIALS 2G/50ML	034218091
VIALS 4G/100ML	034218103 034295042
RECTAL GEL 10%	035356056 035358050
RECTAL GEL 2G	029480023 034556023
RECTAL GEL 4G	034556035 029480035
RECTAL GEL 500MG	033081050 035592017 034757043 026925180 027122151 034390029 034218040
GRANULES FOR RECTAL SUSPENSION 2G	026416091
GRANULES FOR RECTAL SUSPENSION 1,5G	026925038 027122112
RECTAL 100ML	034462046
RECTAL 2G/50ML	034254033
RECTAL 4G/60ML	035075035
RECTAL 4G/100ML	034254045
RECTAL 500ML	032890028
RECTAL FOAM 14G	026925127
RECTAL FOAM 28G	026925115
RECTAL FOAM 2G	026925089 032890030 027122136 034218065

RECTAL FOAM 4G	026925077 027122148 034218053
RECTAL FOAM 1G	026416267 026416279
RECTAL SUSPENSION 1,5G	034218038
RECTAL SUSPENSION 1G/100ML	027130020
RECTAL SUSPENSION 2G	027122062 034836027 034757029
RECTAL SUSPENSION 2G/100ML	027130032
RECTAL SUSPENSION 2G/50ML	034556062 034298036 034336038
RECTAL SUSPENSION 4G	027122098 034757031 026925141
RECTAL SUSPENSION 4G/100ML	027130044 034556074 034336040 034298048
RECTAL SUPPOSITORY 1G	026416305 027130069
RECTAL SUPPOSITORY 400MG	027122011 027122023 027122035
RECTAL SUPPOSITORY 500MG	034254058 026416127 026416139 034298051 033292044 027308067

	029480074
	034295055
	034336053
	029050010
	033256049
	035386059
	034218115
	034462059
	033529049
	035075047
	026925154
	034556086
	027357096
	033763032
	035650011
	035650062
	035650023
	035650035
	035650047
	035650050

Abbreviations: NDC = National drug code; SmPC= summary of product characteristics.

Supplement, Table 3 Number of true positive, false positive, true negative and false negative cases for each algorithm developed for identification of the 83 CD patients

Algorithms	TP	FP	TN	FN
1	76	10	530	7
2	76	12	528	7
3	82	15	525	1
4	59	11	529	24
5	80	12	528	3

Legend= CD= Crohn's Disease; FN= false negative; FP= false positive; TN= true negative; TP= true positive.

Supplement, Table 4 Number of true positive, false positive, true negative and false negative cases for each algorithm developed for identification of 51 UC patients

Algorithms	TP	FP	TN	FN
1	46	45	527	5
2	47	47	525	4
3	48	48	524	3
4	33	35	537	18
5	38	21	551	13

Legend= FN= false negative; FP= false positive; TN= true negative; TP= true positive; UC=ulcerative colitis.