

**ANAL**

**Do not report MedDRA preferred term, please report the verbatim term!**

<b>Verbatim term</b>	<b>MedDRA Preferred Term (PT)</b>
Anal abscess	Anal abscess
Bowen's disease	Bowen's disease
Anal bruising	Contusion
Anal discharge	Rectal discharge
Anal edema	Oedema
Anal erythema	Erythema
Anal fissure	Anal fissure
Anal fistula	Anal fistula
Anal hemorrhoids	Haemorrhoids
Anal intraepithelial neoplasia 1 (biopsy)	Anogenital dysplasia
Anal intraepithelial neoplasia 2 (biopsy)	Anogenital dysplasia
Anal itching	Anal pruritis
Anal leukoplakia	Anal leukoplakia
Anal mass	Mass
Anal pain	Proctalgia
Anal mucosal abrasion	Anal injury
anal pain caused by insertion of study product	Procedural pain
Anal mucosal erosion	Anal erosion
Anal ulcer	Anal ulcer
Anal warts	Anorectal Human Papillomavirus Infection
Anorectal pruritis	Anal pruritis
External anal condyloma	Anorectal Human Papillomavirus Infection
External hemorrhoid	Haemorrhoids
Hemorrhoid	Haemorrhoids
intermittent pain at site of perianal skin	proctalgia
Internal anal condyloma	Anorectal Human Papillomavirus Infection
internal hemorrhoid	Haemorrhoids
Anal Low grade squamous intraepithelial lesion (cytology)	Anogenital dysplasia
perianal abscess	Anal abscess
Perianal dermatitis	Dermatitis
Perianal dermatophyte infection	Anal fungal infection
Perianal ecchymosis	Anal haemorrhage
Perianal fistula	Anal fistula
Perianal fungal skin infection	Anal fungal infection
perianal irritation	Anorectal discomfort
Perianal itch	Anal pruritis
Perianal itching	Anal pruritis
perianal pain	Proctalgia
Perianal purpura	Purpura
perianal skin tear	Laceration
thrombosed hemorrhoid	Haemorrhoids
Anal intraepithelial neoplasia 3 (biopsy)	Anogenital dysplasia

bleeding internal hemorrhoid	Haemorrhoidal haemorrhage
<b>COLORECTAL</b>	
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Verbatim term	MedDRA Preferred Term (PT)
abdominal distension	Abdominal distension
bowel urgency	Defaecation urgency
bowel urgency after study product use	Defaecation urgency
Change in stool color	Faeces discoloured
change in stool consistency	Abnormal faeces
clay colored stool	Faeces discoloured
diarrhea	Diarrhoea
diarrhea - due to procedure	Post procedural diarrhoea
dull rectal pain	proctalgia
effluent from enema	Post procedural drainage
Fecal incontinence	Faecal incontinence
fecal urgency	Defaecation urgency
fecal urgency associated with diarrhea	Diarrhoea
flatulence	Flatulence
flatulence after study gel use	Flatulence
flatulence with bowel movements	Flatulence
increased bowel movement frequency	Frequent bowel movements
increased bowel movements	Frequent bowel movements
increased gas/flatulence	Flatulence
loose stool	Diarrhoea
loose stool - due to study product application	Post procedural diarrhoea
lower abdominal bloating after study gel use	Abdominal distension
mucositis - rectal erythema	proctitis
nocturnal bowel movements	Bowel movement irregularity
soft stool	soft stools
pain during defecation	Painful defecation
pain, rectum	proctalgia
painful defecation	Painful defaecation
proctalgia	Proctalgia
purulent anal discharge	Rectal discharge
rectal discharge	Rectal discharge
rectal itching	Pruritis
rectal mucosa abrasion	mucosal excoriation
rectal mucosa bleeding	Rectal haemorrhage
rectal mucosa erythema	Erythema
rectal polyp	rectal polyp
rectal tenesmus	rectal tenesmus
rectal ulceration	Rectal ulcer
rectal Urgency	Defaecation urgency

rectal urgency associated with diarrhea	Diarrhoea
stool consistency change (stickier and pasty)	Abnormal faeces
urgency to move bowels	Defaecation urgency
<b>SEXUALLY TRANSMITTED INFECTIONS</b>	
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<b>Verbatim term</b>	<b>MedDRA Preferred Term (PT)</b>
anal syphilis	anal syphilis
anal HSV	proctitis herpes
perianal HSV	genital herpes
lymphogranuloma venerum	lymphogranuloma venerum
lymphogranuloma venerum lymphadenitis	lymphogranuloma venerum
lymphogranuloma venerum proctitis	lymphogranuloma venerum
Rectal Chlamydia	Proctitis chlamydia
Rectal Gonorrhoea	Proctitis gonococcal
Syphilis (chancre)	Syphilis
Syphilis (condyloma lata)	Syphilis
<b>OTHER GASTROINTESTINAL VERBATIM TERMS</b>	
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<b>Verbatim term</b>	<b>MedDRA Preferred Term (PT)</b>
anorectal bleeding	Rectal hemorrhage
aphthous ulcer in upper oral gutter	Aphthous stomatitis
abdominal bloating	Abdominal distension
abdominal cramping	Abdominal pain
abdominal cramps	Abdominal pain
abdominal pain	Abdominal pain
acid reflux	Gastroesophageal reflux disease
bad breath	Breath odour
Bloating	Abdominal distension
bloating (related to sigmoidoscopy)	Abdominal distension
blood in stool with frank red blood	Haematochezia
Cramps - Abdominal	Abdominal pain
dry throat	Dry throat
foul taste, throat	Dysgeusia
gastroenteritis	Gastroenteritis
GI bleed	Gastrointestinal haemorrhage
Hematochezia	haematochezia
lower abdominal pain	Abdominal pain lower
melena	Melaena
nausea	Nausea
pilonidal cyst	Pilonidal cyst
right sided lower abdominal pain	Abdominal pain lower
right upper quadrant pain	Abdominal pain upper

stomach cramping	Abdominal pain upper
stomachache	Abdominal pain upper
viral gastroenteritis	Gastroenteritis viral

**PROBLEMATIC VERBATIM TERMS**

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<b>Verbatim term</b>	<b>MedDRA Preferred Term (PT)</b>	<b>COMMENTS</b>
Abdominal pain secondary to abdominal bloating	abdominal distension	The reported term should be abdominal bloating. The pain should be listed as a sx of the bloating in the comments field.
Anal carcinoma in situ	Anal cancer stage 0	Clinically, "Anal intraepithelial neoplasia 3" and "Anal carcinoma in situ" are the same. However "anal carcinoma in situ" will map to "anal cancer stage 0" while "anal intraepithelial neoplasia 3" maps to "anogenital dysplasia". Preference would be to report as "anal intraepithelial neoplasia 3" if possible.
Anal HSV	Proctitis herpes	Anal HSV will map to "Proctitis herpes" and should be distinguished from "perianal herpes" which maps to "genital herpes". "Anal HSV" should only be reported if there is involvement of the anal or rectal mucosa.
anal HSV ulcer	Proctitis herpes	Anal ulcer HSV will map to "Proctitis herpes". Alternatively "perianal herpes" maps to "genital herpes".
Gas	Flatulence	The term gas will automatically map to a meddra preferred term of "flatulence". However, depending on symptoms reported by the participant "abdominal pain" or even "distension" may be more accurate.
gas pain	Flatulence	The term gas will automatically map to a meddra preferred term of "flatulence". However, depending on symptoms reported by the participant "abdominal pain" or even "distension" may be more accurate.
Pain - abdomen & back	not codable	This would generate a query to separate the multiple anatomic locations
Rectal friability	not codable	No term in MedDRA in Meddra exists for rectal friability. Currently, would ask clinican to query/code to Anorectal disorder.
Anal skin tag	Anal skin tag	If the site specifies "Anal Skin Tag" it will map to the preferred term of "Anal Skin Tag". If the site only reports skin tag, it will map to "acrochordon".
study product residue,greasy anal residue sensation	medication residue present	"Medication residue" can be captured, but "Residue sensation" can't be MedDRA coded - is the site trying to report that the ppt feels 'the sensation' of residue (similar to burning sensation, sensation of heaviness) or is residue is actually present? We only want one sx or dx per AE CRF.
ASCUS (atypical cells of uncertain significance)	not codable	This requires anatomical location. ASCUS is an exact match in the MedDRA dictionary to PT cervical dysplasia. Would generate query

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epithelial disruption	not codable	Requires anatomic location (for example - specify anal). Also "epithelial disruption" does not map to any specific term in MedDRA and would generate query. Alternatives could include "ulcer", "erosion", "excoriation", or "abrasion".
mucosal disruption	not codable	See "epithelial disruption"