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| **ANAL** | |
| **Do not report MedDRA preferred term, please report the verbatim term!** | |
| **Verbatim term** | **MedDRA Preferred Term (PT)** |
| 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 pruritus |
| 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 pruritus |
| 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 pruritus |
| Perianal itching | Anal pruritus |
| perianal pain | Proctalgia |
| Perianal purpura | Purpura |
| perianal skin tear | Laceration |
| thrombosed hemorrhoid | Haemorrhoids |
| Anal intraepithelial neoplasia 3 (biopsy) | Anogenital dysplasia |

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| bleeding internal hemorrhoid | Haemorrhoidal haemorrhage |
| Anal terms added to 20.1 for consideration: |  |
|  | Anal candidiasis |
|  | Anal dilation |
|  | Eczema |
|  | Anal erosion |
|  | Anal hypoaesthesia |
|  | Anal incontinence |
|  | Anal inflammation |
|  | Anal necrosis |
|  | Anal paraesthesia |
|  | Anal polyp |
|  | Anal prolapse |
|  | Anal spasm |
|  | Anal palpillitis |
|  | Anal tinea |
|  | Anogenital warts |
|  | Anal skin tag |
|  | Anal injury |
|  | Anal stenosis |
|  | Anal trichiasis |
|  | Anal ulcer haemorrhage |
|  | Anorectal cellulitis |
|  | Anorectal infection |
|  | Anorectal infection bacterial |
|  | Anorectal stenosis |
|  | Anorectal swelling |
|  | Anorectal ulcer |
|  | Haemorrhoids thrombosed |
|  | Anorectal ulcer |
|  | Anorectal varices |
|  | Anorectal varices haemorrhage |
|  | Anorectal disorder |
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| **COLORECTAL** | |
| **Do not report MedDRA preferred term, please report the verbatim term!** | |
| **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 | Pruritus |
| 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 |

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| rectal urgency associated with diarrhea | Diarrhoea |
| stool consistency change (stickier and pasty) | Abnormal faeces |
| urgency to move bowels | Defaecation urgency |
| Colorectal terms added to 20.1 for consideration: |  |
|  | Rectal abscess |
|  | Colorectal cancer |
|  | Colorectal carcinoma |
|  | Rectal spasm |
|  | Rectal fissure |
|  | Rectal injury |
|  | Rectal obstruction |
|  | Rectal neoplasm |
|  | Rectal perforation |
|  | Rectal prolapse |
|  | Rectal stenosis |
|  | Rectal tenesmus |
|  | Rectal ulcer haemorrhage |
| **SEXUALLY TRANSMITTED INFECTIONS** | |
| **Do not report MedDRA preferred term, please report the verbatim term!** | |
| **Verbatim term** | **MedDRA Preferred Term (PT)** |
| anal syphilis | Syphilis anal |
| anal HSV | proctitus herpes |
| perianal HSV | genital herpes |
| lymphogranuloma venerum | lymphogranuloma venereum |
| lymphogranuloma venerum lymphadenitis | lymphogranuloma venereum |
| lymphogranuloma venerum proctitis | lymphogranuloma venerum |
| Rectal Chlamydia | Proctitis chlamydia |
| Rectal Gonorrhea | Proctitis gonococcal |
| Syphilis (chancre) | Syphilis |
| Syphilis (condyloma lata) | Syphilis |
| **OTHER GASTROINTESTINAL VERBATIM TERMS** | |
| **Do not report MedDRA preferred term, please report the verbatim term!** | |
| **Verbatim term** | **MedDRA Preferred Term (PT)** |
| 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 | Gastrooesophageal 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 |
|  | Gastrointestinal necrosis |

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| **PROBLEMATIC VERBATIM TERMS** | | |
| **Do not report MedDRA preferred term, please report the verbatim term!** | | |
| **Verbatim term** | **MedDRA Preferred Term (** | **COMMENTS** |
| 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 | Proctitus 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 | Proctitus 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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| **PROBLEMATIC VERBATIM TERMS** | | |
| **Do not report MedDRA preferred term, please report the verbatim term!** | | |
| **Verbatim term** | **MedDRA Preferred Term (** | **COMMENTS** |
| 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" |