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Image



QOL

[illegible]

mTOR inhibitor-associated stomatitis
mIAS

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Oral Supportive Care for Cancer Committee.:
 ○○○○○○○○○○○○○○○○○○○○OSC3○○○○○○○○○○○○○. 2015○○○○

CTCAE v3.0
v4.0 1 CTCAE v3.0

Image

CTCAE	Grade				
	1	2	3	4	5
v 3.0 (診察所見)	粘膜の紅斑	斑状潰瘍または偽膜	融合した潰瘍または偽膜 わずかな外傷で出血	組織の壊死 顕著な自然出血	死亡
(機能所見)	わずかな症状で摂食に影響なし	症状があるが、食べやすく加工した食事を摂取し嚥下することはできる	症状があり、十分な栄養や水分の経口摂取ができない	生命を脅かす症状がある	
v 4.0	症状がないまたは軽度治療を要さない	中等度の疼痛 経口摂取に支障がない 食事の変更を要する	高度の疼痛 経口摂取に支障がある	生命を脅かす 緊急処置を要する	死亡

CTCAE v3.0 参照 JCOG/JSCO

9th Suppl. 2, 1, 2004 / JCOG Web <http://www.jcog.jp/>

CTCAE v4.0 参照 JCOG/JCOG Web <http://www.jcog.jp/>

CTCAE v3.0

Grade 0 5 6

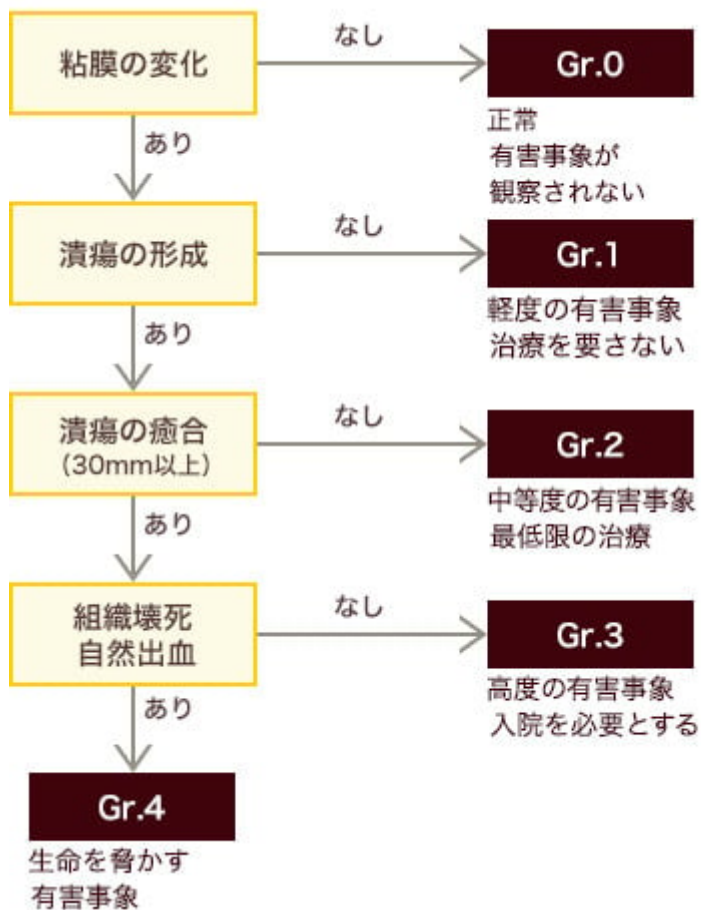
CTCAE v3.0 1

CTCAE v3.0

1 CTCAE v3.0

Image

口腔粘膜炎の評価



Oral Supportive Care for Cancer Committee.:

口腔粘膜炎の評価基準は、OSC3（Oral Supportive Care for Cancer Committee, 2015）を参照する。

Nearest Match

口腔粘膜炎の評価基準は、Grade 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100/101/102/103/104/105/106/107/108/109/110/111/112/113/114/115/116/117/118/119/120/121/122/123/124/125/126/127/128/129/130/131/132/133/134/135/136/137/138/139/140/141/142/143/144/145/146/147/148/149/150/151/152/153/154/155/156/157/158/159/160/161/162/163/164/165/166/167/168/169/170/171/172/173/174/175/176/177/178/179/180/181/182/183/184/185/186/187/188/189/190/191/192/193/194/195/196/197/198/199/200/201/202/203/204/205/206/207/208/209/210/211/212/213/214/215/216/217/218/219/220/221/222/223/224/225/226/227/228/229/230/231/232/233/234/235/236/237/238/239/240/241/242/243/244/245/246/247/248/249/250/251/252/253/254/255/256/257/258/259/260/261/262/263/264/265/266/267/268/269/270/271/272/273/274/275/276/277/278/279/280/281/282/283/284/285/286/287/288/289/290/291/292/293/294/295/296/297/298/299/300/301/302/303/304/305/306/307/308/309/310/311/312/313/314/315/316/317/318/319/320/321/322/323/324/325/326/327/328/329/330/331/332/333/334/335/336/337/338/339/340/341/342/343/344/345/346/347/348/349/350/351/352/353/354/355/356/357/358/359/360/361/362/363/364/365/366/367/368/369/370/371/372/373/374/375/376/377/378/379/380/381/382/383/384/385/386/387/388/389/390/391/392/393/394/395/396/397/398/399/400/401/402/403/404/405/406/407/408/409/410/411/412/413/414/415/416/417/418/419/420/421/422/423/424/425/426/427/428/429/430/431/432/433/434/435/436/437/438/439/440/441/442/443/444/445/446/447/448/449/450/451/452/453/454/455/456/457/458/459/460/461/462/463/464/465/466/467/468/469/470/471/472/473/474/475/476/477/478/479/480/481/482/483/484/485/486/487/488/489/490/491/492/493/494/495/496/497/498/499/500/501/502/503/504/505/506/507/508/509/510/511/512/513/514/515/516/517/518/519/520/521/522/523/524/525/526/527/528/529/530/531/532/533/534/535/536/537/538/539/540/541/542/543/544/545/546/547/548/549/550/551/552/553/554/555/556/557/558/559/560/561/562/563/564/565/566/567/568/569/570/571/572/573/574/575/576/577/578/579/580/581/582/583/584/585/586/587/588/589/590/591/592/593/594/595/596/597/598/599/600/601/602/603/604/605/606/607/608/609/610/611/612/613/614/615/616/617/618/619/620/621/622/623/624/625/626/627/628/629/630/631/632/633/634/635/636/637/638/639/640/641/642/643/644/645/646/647/648/649/650/651/652/653/654/655/656/657/658/659/660/661/662/663/664/665/666/667/668/669/670/671/672/673/674/675/676/677/678/679/680/681/682/683/684/685/686/687/688/689/690/691/692/693/694/695/696/697/698/699/700/701/702/703/704/705/706/707/708/709/710/711/712/713/714/715/716/717/718/719/720/721/722/723/724/725/726/727/728/729/730/731/732/733/734/735/736/737/738/739/740/741/742/743/744/745/746/747/748/749/750/751/752/753/754/755/756/757/758/759/760/761/762/763/764/765/766/767/768/769/770/771/772/773/774/775/776/777/778/779/780/781/782/783/784/785/786/787/788/789/790/791/792/793/794/795/796/797/798/799/800/801/802/803/804/805/806/807/808/809/810/811/812/813/814/815/816/817/818/819/820/821/822/823/824/825/826/827/828/829/830/831/832/833/834/835/836/837/838/839/840/841/842/843/844/845/846/847/848/849/850/851/852/853/854/855/856/857/858/859/860/861/862/863/864/865/866/867/868/869/870/871/872/873/874/875/876/877/878/879/880/881/882/883/884/885/886/887/888/889/890/891/892/893/894/895/896/897/898/899/900/901/902/903/904/905/906/907/908/909/910/911/912/913/914/915/916/917/918/919/920/921/922/923/924/925/926/927/928/929/930/931/932/933/934/935/936/937/938/939/940/941/942/943/944/945/946/947/948/949/950/951/952/953/954/955/956/957/958/959/960/961/962/963/964/965/966/967/968/969/970/971/972/973/974/975/976/977/978/979/980/981/982/983/984/985/986/987/988/989/990/991/992/993/994/995/996/997/998/999/1000/1001/1002/1003/1004/1005/1006/1007/1008/1009/1010/1011/1012/1013/1014/1015/1016/1017/1018/1019/1020/1021/1022/1023/1024/1025/1026/1027/1028/1029/1030/1031/1032/1033/1034/1035/1036/1037/1038/1039/1040/1041/1042/1043/1044/1045/1046/1047/1048/1049/1050/1051/1052/1053/1054/1055/1056/1057/1058/1059/1060/1061/1062/1063/1064/1065/1066/1067/1068/1069/1070/1071/1072/1073/1074/1075/1076/1077/1078/1079/1080/1081/1082/1083/1084/1085/1086/1087/1088/1089/1090/1091/1092/1093/1094/1095/1096/1097/1098/1099/1100/1101/1102/1103/1104/1105/1106/1107/1108/1109/1110/1111/1112/1113/1114/1115/1116/1117/1118/1119/1120/1121/1122/1123/1124/1125/1126/1127/1128/1129/1130/1131/1132/1133/1134/1135/1136/1137/1138/1139/1140/1141/1142/1143/1144/1145/1146/1147/1148/1149/1150/1151/1152/1153/1154/1155/1156/1157/1158/1159/1160/1161/1162/1163/1164/1165/1166/1167/1168/1169/1170/1171/1172/1173/1174/1175/1176/1177/1178/1179/1180/1181/1182/1183/1184/1185/1186/1187/1188/1189/1190/1191/1192/1193/1194/1195/1196/1197/1198/1199/1200/1201/1202/1203/1204/1205/1206/1207/1208/1209/1210/1211/1212/1213/1214/1215/1216/1217/1218/1219/1220/1221/12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有害事象	Short Name	Grade				
		1	2	3	4	5
粘膜炎/ 口内炎 (診察所見)	Mucositis (clinical exam)	粘膜の紅斑	斑状潰瘍 または偽膜	融合した潰瘍 または偽膜; わずかな 外傷で出血	組織の壊死; 顕著な 自然出血; 生命を脅かす	死亡
粘膜炎/ 口内炎 (機能/症状)	Mucositis (functional/ symptomatic)	わずかな症状 で摂食に 影響なし	症状があるが, 食べやすく 加工した食事を 摂取し嚥下する	症状があり, 十分な栄養や 水分の経口 摂取ができない	生命を脅かす 症状がある	死亡

日本語版CTCAE V3.0 日本語訳 JCOG/JSCO - 2004年10月27日
Common Terminology Criteria for Adverse Events v3.0 (CTCAE v3.0)

CTCAE v3.0 日本語訳

Grade 1

Grade 2

潰瘍の最大径が30mm未満
潰瘍が深さ1cm未満
潰瘍が深さ1cm未満でGr.2未満

Grade 3

潰瘍の最大径が30mm以上
潰瘍が深さ1cm以上

Grade 4

潰瘍の最大径が30mm以上
潰瘍が深さ1cm以上
潰瘍が深さ1cm以上でGr.4未満

Grade 1

Grade 1

Image

Grade1 粘膜の紅斑

粘膜の発赤、浮腫様変化
ただし、びらん・潰瘍の形成を伴わない



Gr.1 左軟口蓋部の発赤



Gr.1 舌の浮腫様変化



Gr.1 口蓋全体の発赤

Grade 1

Grade 1

Grade 2

3 Grade 2

Image

Grade2 斑状潰瘍または偽膜

- 斑状で限局的、1個の大きさは30mm未満
- 限局的とは複数の亜部位をまたがない範囲
- 複数の亜部位にそれぞれ潰瘍があっても、各部分ごとに散発する場合はGr.2とする



Gr.2 左軟口蓋部の潰瘍



Gr.2 右頬粘膜に潰瘍



Gr.2 口蓋と左頬粘膜に潰瘍

Grade 2

Gr.2→Gr.3

Grade 2

NSAIDs

Oral Supportive Care for Cancer Committee.:
OSC3. 2015

Grade 3

4 Grade 3

Image

Grade3

癒合した潰瘍・偽膜
わずかな外傷で出血

- 30mm以上の広範囲に広がるもの
- 複数の垂部位にまたがり広がるもの
- 範囲が大きく、複数垂部位にわたる潰瘍の場合、嚥下障害や強い疼痛と関連する



Gr.3 口蓋部の潰瘍



Gr.3 口蓋垂周囲に潰瘍・偽膜



Gr.3 左頬粘膜に潰瘍・潰瘍

Grade 3

口蓋部の潰瘍、口蓋垂周囲に潰瘍・偽膜、左頬粘膜に潰瘍・潰瘍

Grade 3

口蓋部の潰瘍、口蓋垂周囲に潰瘍・偽膜、左頬粘膜に潰瘍・潰瘍

口蓋部の潰瘍

□□□□□□□□□□

PEG00000000000000

OSC3. 2015

5 Grade 4

組織壊死
顕著な自然出血

- 口腔内全体に広がる潰瘍・偽膜
- 潰瘍面からの持続する出血
- 広範囲にみとめるコアグラ様痂皮（表面乾燥等による痂皮の剥がれに伴う出血は除外）



Gr.4 口蓋全体に拡がる偽膜



Gr.4 広範囲に拡がる出血

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Grade 4

Oral Supportive Care for Cancer Committee.:

Grade 4 OSC3 Grade 4 OSC3. 2015

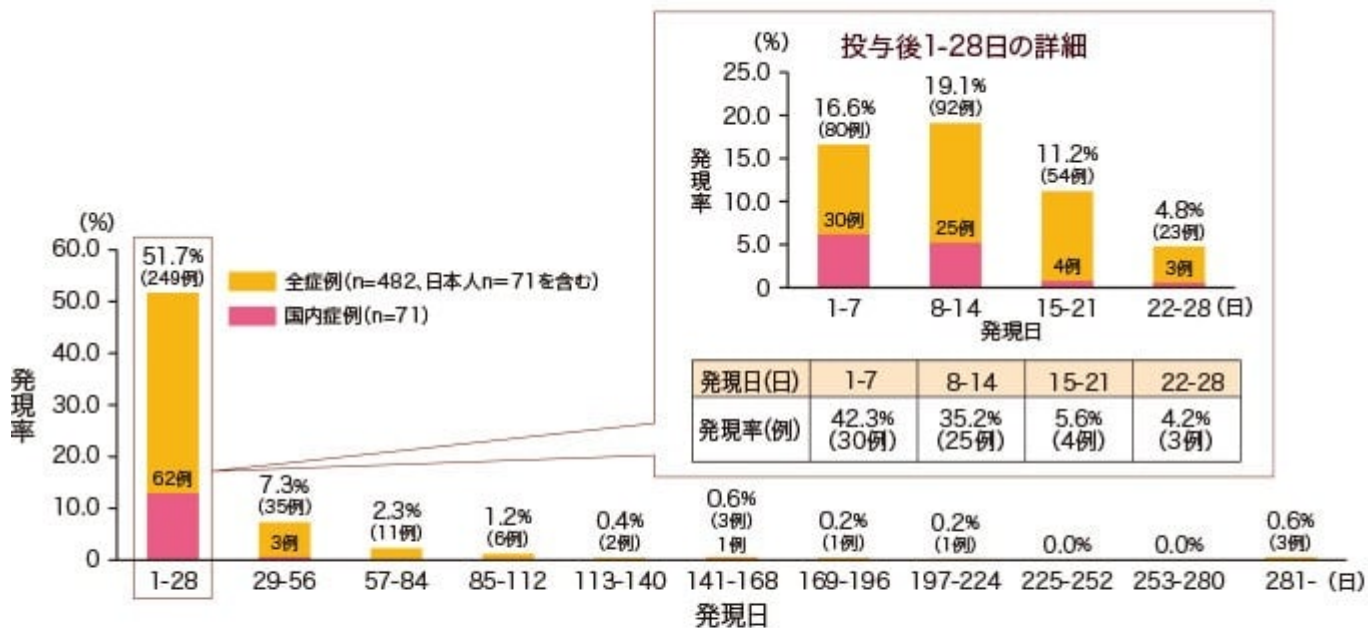
Grade 4

Grade 4 BOLERO-2 Grade 4 482 Grade 4 311 Grade 4 64.5% Grade 4 Grade 1 Grade 2 Grade 3/4 Grade 3/4 39 Grade 4 8.1% Grade 4 Grade 1 Grade 2 Grade 3/4 Grade 3/4 1 Grade 4 28 Grade 4 51.7% Grade 4 Grade 4 6

6

Image

BOLERO-2試験



BOLERO-2試験国内症例(n=71)

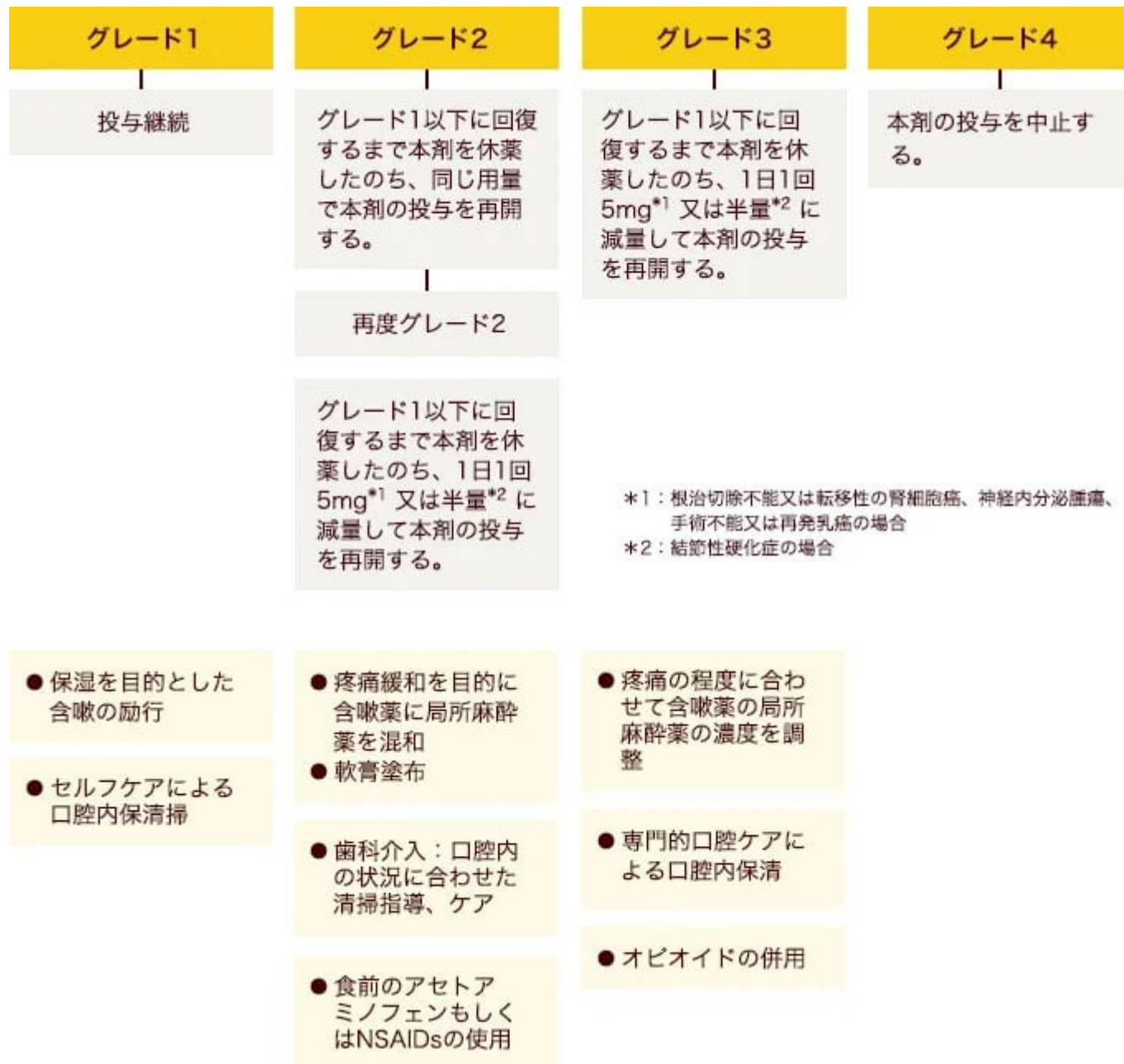
発現日(日)	1-28	29-56	57-84	85-112	113-140	141-168	169-196	197-224	225-252	253-280	281-
発現率(例)	78.3% (62例)	4.2% (3例)	0%	0%	0%	1.4% (1例)	0%	0%	0%	0%	0%

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7

7 **Grade**

Image



3 口腔ケア

Image

Source URL: https://loadtest.pro.novartis.com/products/afinitor/bc/stomatitis