

高雄榮民總醫院

口咽癌診療原則

2020年04月29日 第一版

頭頸癌醫療團隊擬訂

注意事項：這個診療原則主要作為醫師和其他保健專家診療癌症病人參考之用。假如你是一個癌症病人，直接引用這個診療原則並不恰當，只有你的醫師才能決定給你最恰當的治療。

會議討論

上次會議：2019/03/06

本共識與上一版的差異

上一版	新版
1. 若有PET，可不做Bone scan(p1) 2. 建立P16(+)/P16(-) Staging(p1) 3. Positive margin合併 ENE(Extranodal extension)欄位 4. 新增獨立Tonsil 治療指引(p8) 5. M1移除CDDP + F + Cetuximab；於 P15呈現即可(p10)	1. Survey時可加上Chest CT及戒菸。 2. 有接受RT者，後續追蹤時加驗TSH、 free T4。 3. P16(-)的病患，Clinical T4b不以手術 為主要治療選項。 4. P16(+)的病患，若Clinical N3 or T4a， 建議CCRT。 5. P16(+)的病患，若手術後無adverse feature，建議Follow-up or RT。 6. 在Recurrent, unresectable, metastatic的化療Regimen提升immune therapy順序，並加入合併使用化療的 選項。

Oropharyngeal (P16 negative) cancer

Clinical staging AJCC 8th

Oropharyngeal (p16 negative) cancer TNM clinical staging AJCC UICC 2017

Primary tumor (T)	
Oropharynx (p16-)	
T category	T criteria
TX	Primary tumor cannot be assessed
Tis	Carcinoma <i>in situ</i>
T1	Tumor 2 cm or smaller in greatest dimension
T2	Tumor larger than 2 cm but not larger than 4 cm in greatest dimension
T3	Tumor larger than 4 cm in greatest dimension or extension to lingual surface of epiglottis
T4	Moderately advanced or very advanced local disease
T4a	Moderately advanced local disease. Tumor invades the larynx, extrinsic muscle of tongue, medial pterygoid, hard palate, or mandible.*
T4b	Very advanced local disease. Tumor invades lateral pterygoid muscle, pterygoid plates, lateral nasopharynx, or skull base or encases carotid artery.
* NOTE: Mucosal extension to lingual surface of epiglottis from primary tumors of the base of the tongue and vallecula does not constitute invasion of the larynx.	
Regional lymph nodes (N)	
Clinical N (cN) - Oropharynx (p16-) and hypopharynx	
N category	N criteria
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(-)
N2	Metastasis in a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-); or metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-); or in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-)
N2a	Metastasis in a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-)
N2b	Metastasis in multiple ipsilateral nodes, none larger than 6 cm in greatest dimension and ENE(-)
N2c	Metastasis in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-)
N3	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-); or metastasis in any node(s) and clinically overt ENE(+)
N3a	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-)
N3b	Metastasis in any node(s) and clinically overt ENE(+)
NOTE: A designation of "U" or "L" may be used for any N category to indicate metastasis above the lower border of the cricoid (U) or below the lower border of the cricoid (L). Similarly, clinical and pathological ENE should be recorded as ENE(-) or ENE(+).	

Distant metastasis (M)			
Oropharynx (p16-) and hypopharynx			
M category		M criteria	
M0		No distant metastasis	
M1		Distant metastasis	
Prognostic stage groups			
When T is...	And N is...	And M is...	Then the stage group is...
Tis	N0	M0	0
T1	N0	M0	I
T2	N0	M0	II
T3	N0	M0	III
T1, T2, T3	N1	M0	III
T4a	N0, 1	M0	IVA
T1, T2, T3, T4a	N2	M0	IVA
Any T	N3	M0	IVB
T4b	Any N	M0	IVB
Any T	Any N	M1	IVC

TNM: tumor, node, metastasis; AJCC: American Joint Committee on Cancer; UICC: Union for International Cancer Control; ENE: extranodal extension.

Oropharyngeal (P16 negative) cancer

Pathological staging AJCC 8th

Oropharyngeal (p16 negative) cancer TNM pathological staging AJCC UICC 2017

Primary tumor (T)	
Oropharynx (p16-)	
T category	T criteria
TX	Primary tumor cannot be assessed
Tis	Carcinoma <i>in situ</i>
T1	Tumor 2 cm or smaller in greatest dimension
T2	Tumor larger than 2 cm but not larger than 4 cm in greatest dimension
T3	Tumor larger than 4 cm in greatest dimension or extension to lingual surface of epiglottis
T4	Moderately advanced or very advanced local disease
T4a	Moderately advanced local disease. Tumor invades the larynx, extrinsic muscle of tongue, medial pterygoid, hard palate, or mandible.*
T4b	Very advanced local disease. Tumor invades lateral pterygoid muscle, pterygoid plates, lateral nasopharynx, or skull base or encases carotid artery.
* NOTE: Mucosal extension to lingual surface of epiglottis from primary tumors of the base of the tongue and vallecula does not constitute invasion of the larynx.	
Regional lymph nodes (N)	
Pathological N (pN) - Oropharynx (p16-) and hypopharynx	
N category	N criteria
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(-)
N2	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(+); or larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-); or metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-); or in bilateral or contralateral lymph node(s), none larger than 6 cm in greatest dimension and ENE(-)
N2a	Metastasis in single ipsilateral node 3 cm or smaller in greatest dimension and ENE(+); or a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-)
N2b	Metastasis in multiple ipsilateral nodes, none larger than 6 cm in greatest dimension and ENE(-)
N2c	Metastasis in bilateral or contralateral lymph node(s), none larger than 6 cm in greatest dimension and ENE(-)
N3	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-); or in a single ipsilateral node larger than 3 cm in greatest dimension and ENE(+); or multiple ipsilateral, contralateral or bilateral nodes, any with ENE(+); or a single contralateral node 3 cm or smaller and ENE(+)
N3a	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-)
N3b	Metastasis in a single ipsilateral node larger than 3 cm in greatest dimension

	and ENE(+); or multiple ipsilateral, contralateral or bilateral nodes, any with ENE(+); or a single contralateral node 3 cm or smaller and ENE(+)		
NOTE: A designation of "U" or "L" may be used for any N category to indicate metastasis above the lower border of the cricoid (U) or below the lower border of the cricoid (L). Similarly, clinical and pathological ENE should be recorded as ENE(-) or ENE(+).			
Distant metastasis (M)			
Oropharynx (p16-) and hypopharynx			
M category	M criteria		
M0	No distant metastasis		
M1	Distant metastasis		
Prognostic stage groups			
When T is...	And N is...	And M is...	Then the stage group is...
Tis	N0	M0	0
T1	N0	M0	I
T2	N0	M0	II
T3	N0	M0	III
T1, T2, T3	N1	M0	III
T4a	N0, 1	M0	IVA
T1, T2, T3, T4a	N2	M0	IVA
Any T	N3	M0	IVB
T4b	Any N	M0	IVB
Any T	Any N	M1	IVC

TNM: tumor, node, metastasis; AJCC: American Joint Committee on Cancer; UICC: Union for International Cancer Control; ENE: extranodal extension.

Oropharyngeal (P16 Positive) cancer

Pathological staging AJCC 8th

HPV related oropharyngeal carcinoma TNM clinical staging AJCC UICC 2017

Primary tumor (T)			
T category	T criteria		
T0	No primary identified		
T1	Tumor 2 cm or smaller in greatest dimension		
T2	Tumor larger than 2 cm but not larger than 4 cm in greatest dimension		
T3	Tumor larger than 4 cm in greatest dimension or extension to lingual surface of epiglottis		
T4	Moderately advanced local disease. Tumor invades the larynx, extrinsic muscle of tongue, medial pterygoid, hard palate, or mandible or beyond.*		
Regional lymph nodes (N) - Clinical N (cN)			
N category	N criteria		
NX	Regional lymph nodes cannot be assessed		
N0	No regional lymph node metastasis		
N1	One or more ipsilateral lymph nodes, none larger than 6 cm		
N2	Contralateral or bilateral lymph nodes, none larger than 6 cm		
N3	Lymph node(s) larger than 6 cm		
Distant metastasis (M)			
M category	M criteria		
M0	No distant metastasis		
M1	Distant metastasis		
Prognostic stage groups - Clinical			
When T is...	And N is...	And M is...	Then the stage group is...
T0, T1, or T2	N0 or N1	M0	I
T0, T1, or T2	N2	M0	II
T3	N0, N1, or N2	M0	II
T0, T1, T2, T3, or T4	N3	M0	III
T4	N0, N1, N2, or N3	M0	III
Any T	Any N	M1	IV

HPV: human papillomavirus; TNM: tumor, node, metastasis; AJCC: American Joint Committee on Cancer; UICC: Union for International Cancer Control.

* Mucosal extension to lingual surface of epiglottis from primary tumors of the base of the tongue and vallecula does not constitute invasion of the larynx.

HPV related oropharyngeal carcinoma TNM pathologic staging AJCC UICC 2017

Primary tumor (T)			
T category	T criteria		
T0	No primary identified		
T1	Tumor 2 cm or smaller in greatest dimension		
T2	Tumor larger than 2 cm but not larger than 4 cm in greatest dimension		
T3	Tumor larger than 4 cm in greatest dimension or extension to lingual surface of epiglottis		
T4	Moderately advanced local disease. Tumor invades the larynx, extrinsic muscle of tongue, medial pterygoid, hard palate, or mandible or beyond.*		
Regional lymph nodes (N) - Pathological N (pN)			
N category	N criteria		
NX	Regional lymph nodes cannot be assessed		
pN0	No regional lymph node metastasis		
pN1	Metastasis in four or fewer lymph nodes		
pN2	Metastasis in more than four lymph nodes		
Distant metastasis (M)			
M category	M criteria		
M0	No distant metastasis		
M1	Distant metastasis		
Prognostic stage groups - Pathological			
When T is...	And N is...	And M is...	Then the stage group is...
T0, T1, or T2	N0, N1	M0	I
T0, T1, or T2	N2	M0	II
T3 or T4	N0, N1	M0	II
T3 or T4	N2	M0	III
Any T	Any N	M1	IV

HPV: human papillomavirus; TNM: tumor, node, metastasis; AJCC: American Joint Committee on Cancer; UICC: Union for International Cancer Control.

* Mucosal extension to lingual surface of epiglottis from primary tumors of the base of the tongue and vallecula does not constitute invasion of the larynx.

Carcinoma of Oropharynx

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WORK-UP	STAGING & TREATMENT	FOLLOW-UP
• History & PE • Biopsy & Pathology • Image → MRI*or CT of H&N* or PET → WBBS/ Abd. Sono/ CXR → ± Chest CT* (若有PET，可不作此項檢查) → ± Neck sono → ± EUA with endoscopy/ PES • Dental evaluation → Panorex ± teeth extraction • <u>Multidisciplinary consultation</u> ± Swallowing evaluation • <u>p16 status</u> (*與癌症期別相關之主要檢查) ± Smoking cessation	• (P16-)[T1-2, N0-1, M0] 詳見 Page 2 • (P16-)[T3-4a, N0-1, M0] 詳見 Page 3 • (P16-)[T1-4a, N2-3, M0] 詳見 Page 4 • (P16+)[T1-2, N0-1, M0] (single node=$\leq$3cm) 詳見 Page 5 • (P16+)[T1-2, N1-2, M0] (single node$>$3cm, 2 or more nodes$\leq$6cm) or [T3, N0-2, M0] 詳見 Page 6 • (P16+)[T1-3, N3, M0] or [T4, N0-3, M0] 詳見 Page 7 • Tonsil Page 8 • Very advanced stage 詳見 Page 9, 10	• <u>[Post-Tx within 3-6 months]</u> → Baseline MRI or CT (PET) → Every 1-2 months: PE • <u>[2nd year after Tx]</u> → Every 2-3 months: PE • <u>[3-5 years after Tx]</u> → Every 4-8 months: PE • <u>[5 years after Tx]</u> → Every 12 months: PE • Every year: H & N MRI or CT, CxR, Bone scan & Abd. Sono, Neck Sono ± TSH、free T4(if RT, 6-12 months) as clinically indicated

Carcinoma of Oropharynx(P16-)

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**Clinical T1-2,
N0-1, M0**

Primary treatment

**Definite RT or
CCRT(T1-2 ,N1 only)**

**Resection of primary
± ND, unil. or bil.#**

Pathological features

Adjuvant management

Complete clinical response

Follow-up

Residual disease

Surgery

Adverse features* (-)

Follow-up

Extranodal extension ±
positive margin

CRT^{註1-2}

Positive margin

Re-resection, RT
or CRT ^{註1-2}

Other adverse features

RT or CRT^{註1-2}

依cN status而定,可考慮Elective neck dissection或close follow-up

* Adverse features : Extranodal extension, positive or close margins, pT3 or pT4 primary, N2 or N3 nodal disease, nodal disease in levels IV or V, perineural invasion, vascular embolism lymphatic invasion

Carcinoma of Oropharynx(P16-)

高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page 3 (Ref. 1,2)

**Clinical T3-4a,
N0-1, M0**

Primary treatment

CCRT

**Induction CT
+ CRT or RT^{註1-3}**

**Resection of primary,
ND, unil. or bil.#**

Pathological features

Complete clinical response

Residual disease

Adverse features*(-)

Extranodal extension ±
positive margin

Other adverse features

Adjuvant Management

Follow-up

Surgery if operable

RT^{註1}

CRT or RT^{註1-2}

RT or CRT^{註1-2}

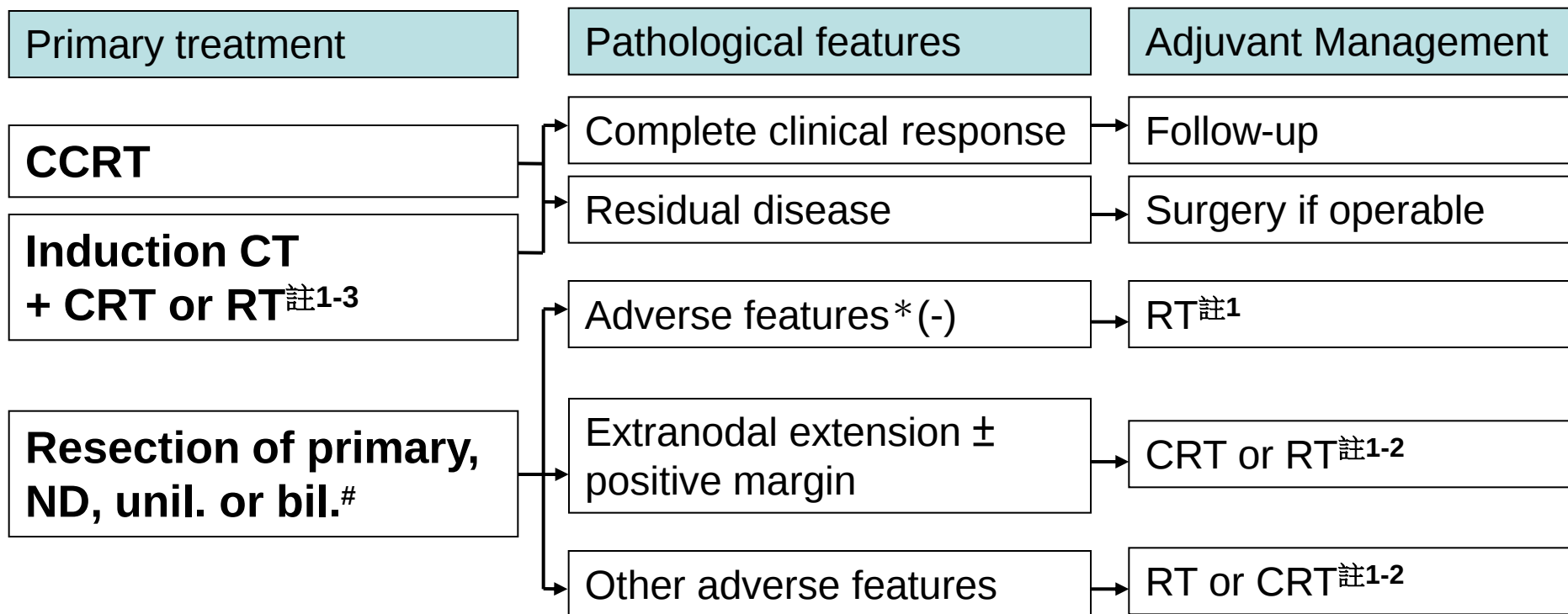
Neck dissection level 依cN status而定。

* Adverse features : Extranodal extension, positive **or close** margins, pT3 or pT4 primary, N2 or N3 nodal disease, nodal disease in levels IV or V, perineural invasion, vascular embolism lymphatic invasion

Carcinoma of Oropharynx(P16-)

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Clinical T1-4a, N2-3, M0

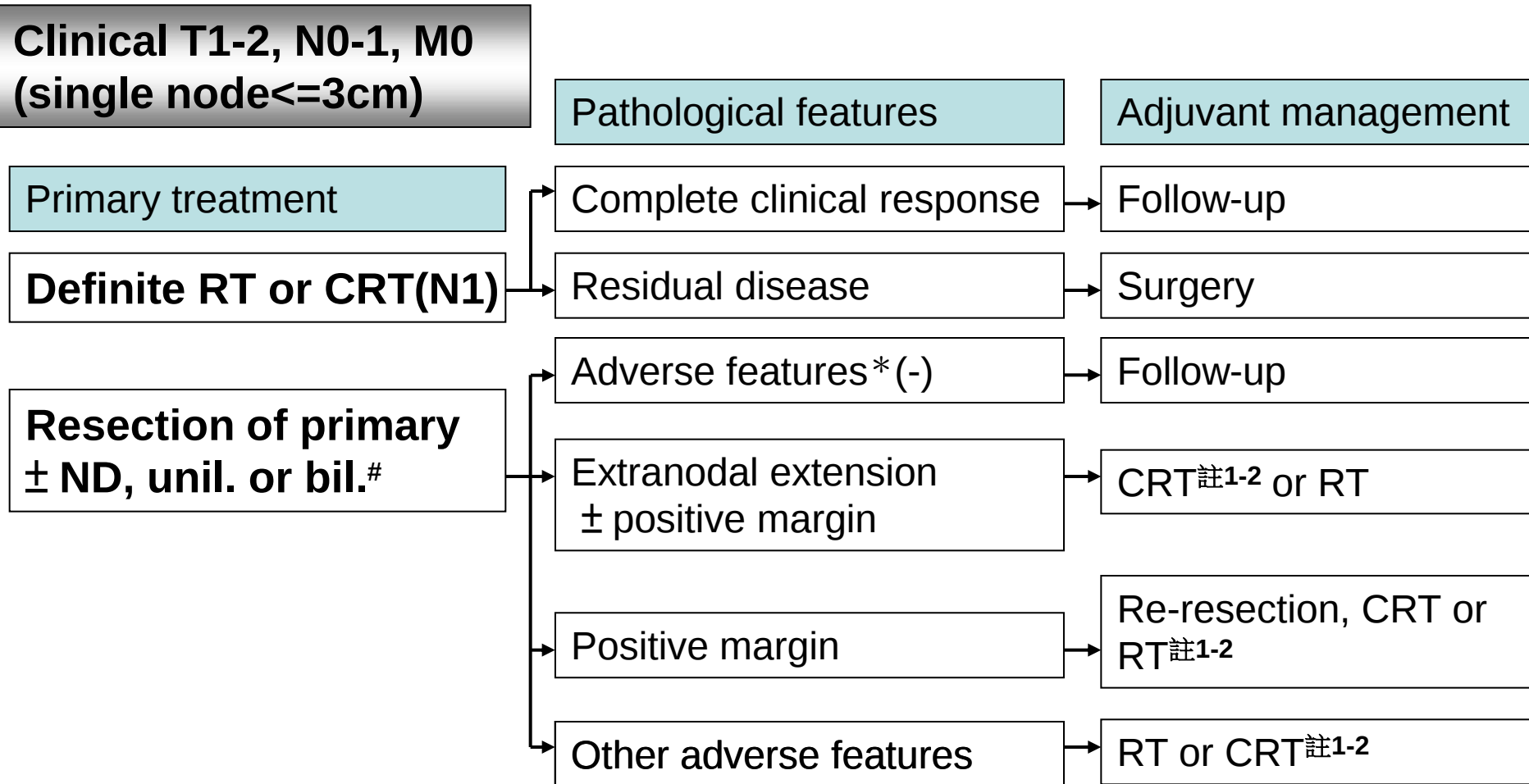


Neck dissection level 依primary部位及cN status而定。

* Adverse features : Extranodal extension, positive or close margins, pT3 or pT4 primary, N2 or N3 nodal disease, nodal disease in levels IV or V, perineural invasion, vascular embolism lymphatic invasion

Carcinoma of Oropharynx (P16+)

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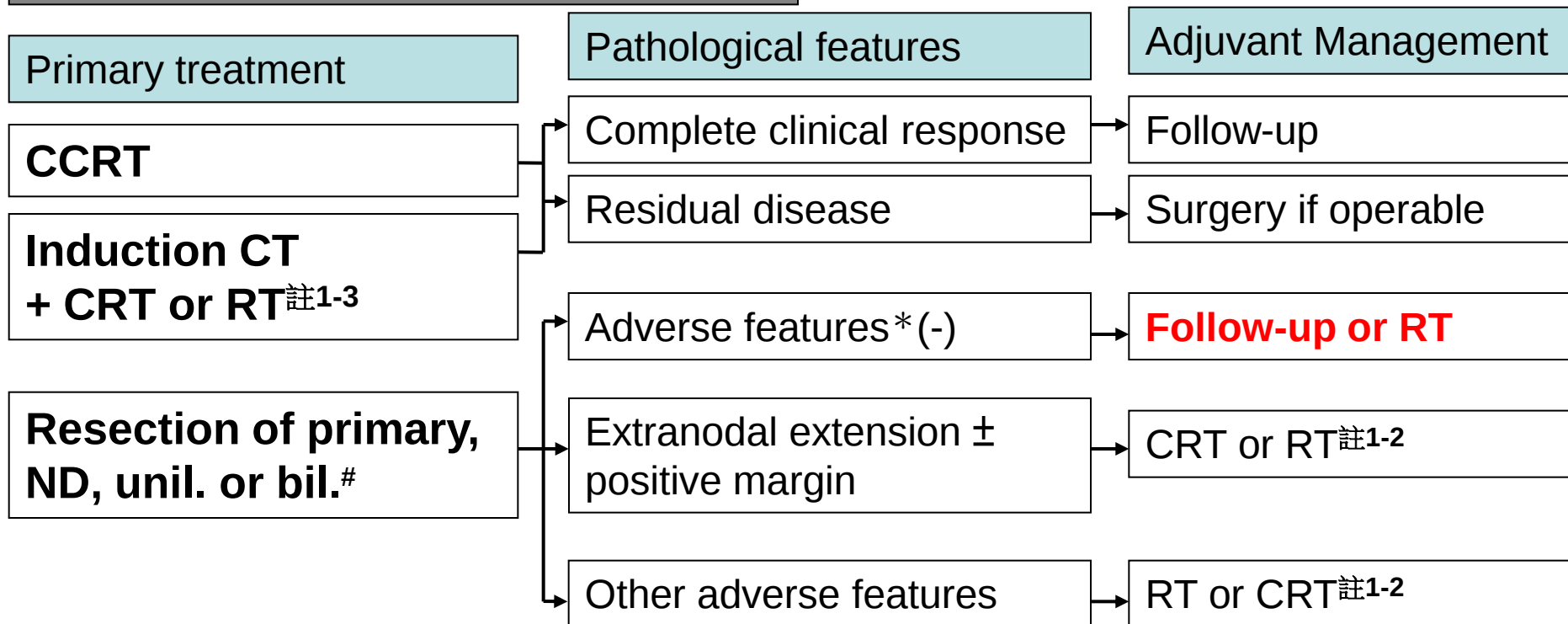
依cN status而定,可考慮Elective neck dissection或close follow-up

* Adverse features : Extranodal extension, positive or close margins, nodal disease in levels IV or V, perineural invasion, lymphovascular invasion

Carcinoma of Oropharynx (P16+)

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Clinical T1-2, N1-2, M0 (single node >3cm, 2 or more nodes ≤6cm) or T3, N0-2, M0



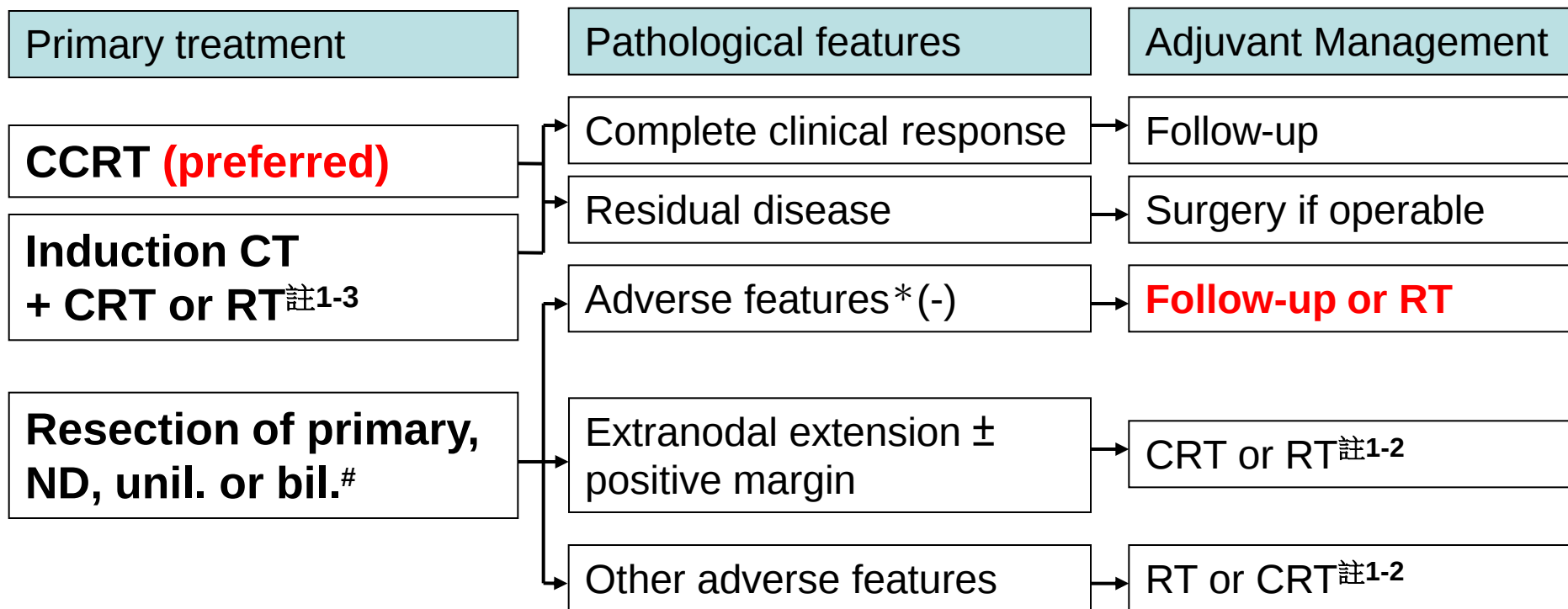
[#] Neck dissection level 依cN status而定。

* Adverse features : Extranodal extension, positive **or close** margins, nodal disease in levels IV or V, perineural invasion, lymphovascular invasion

Carcinoma of Oropharynx (P16+)

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Clinical T1-3,N3, M0 or T4, N0-3, M0



Neck dissection level 依primary部位及cN status而定。

* Adverse features : Extranodal extension, positive **or close** margins, nodal disease in levels IV or V, perineural invasion, lymphovascular invasion

Carcinoma of Oropharynx (Tonsil)

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Clinical any T, any N

Primary treatment

Chemoselection^{註3}

Induction CT(T60P60) x 3

Response

ycT0-2,N0

ycT1-2,N1-2

ycT3-4, anyN or yc anyT, N3

Treatment

Resection of primary ±
ND, unil. or bil.[#]

CRT or surgery

Pathological features

Positive margin

Free margin, N0

Free margin, LN ≤ 3, ENE
<2, ENE < 1mm

Free margin, LN > 3 or
ENE ≥ 2 or ENE ≥ 1mm

Adjuvant Management

CRT^{註1-2}

Adjuvant CT(T60P60) x 2^{註3}

Adjuvant CT(T60P60) x 2^{註3}

CRT^{註1-2} < 65 Gy

Neck dissection level 依primary部位及cN status而定。

Carcinoma of Oropharynx

高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page 9 (Ref. 1,2)

P16(-), Clinical T4b, any N or unresectable nodal disease or inoperable patient status

Management

PS 0-1

CCRT or RT 註1-2

Induction CT 註3 + RT or CRT 註1-2

PS 2

Definite RT 註1 ± CT 註2

PS 3

Palliative RT 註1

Single agent palliative CT 註3

Best supportive care

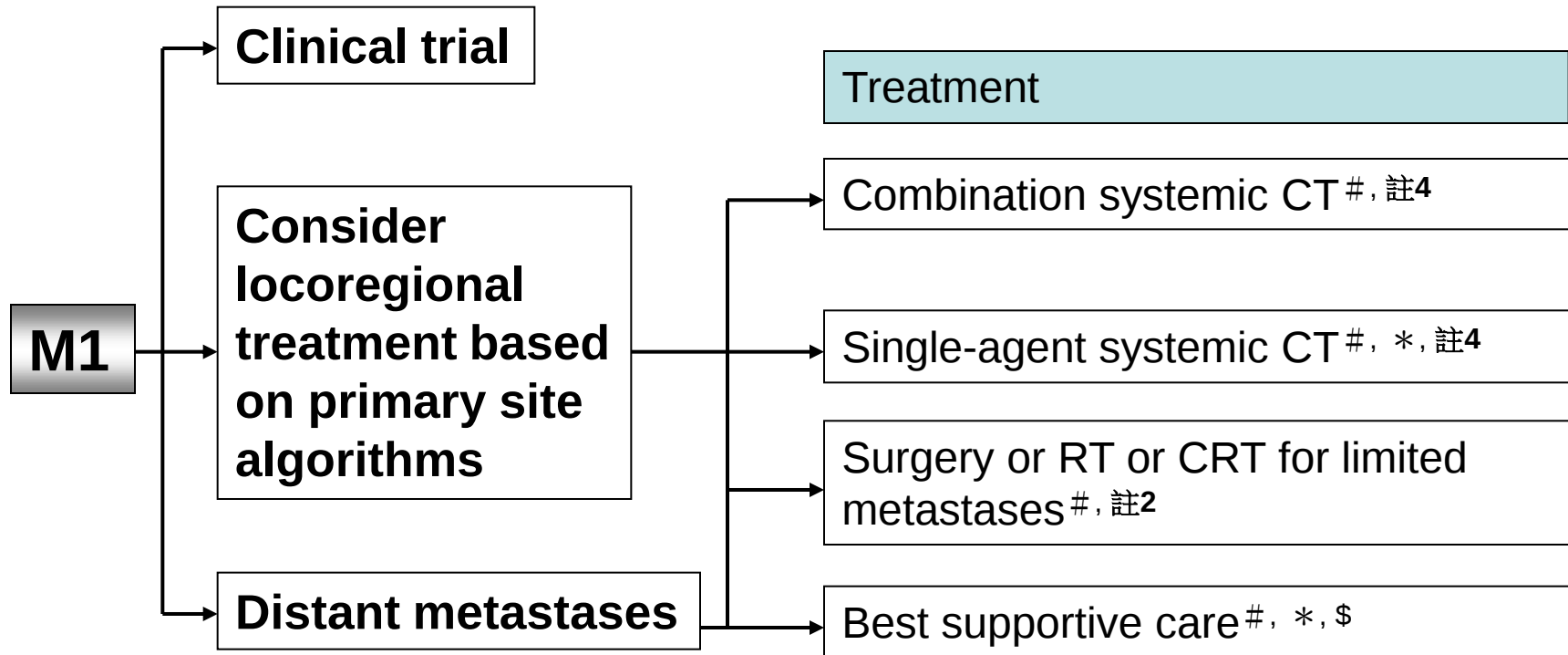
ECOG Performance Status 0-1 註6

ECOG Performance Status 2

ECOG Performance Status 3

Carcinoma of Oropharynx

高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page10 (Ref. 1,15-17)



ECOG Performance Status 0-1^{註6}

* ECOG Performance Status 2

\$ ECOG Performance Status 3

Carcinoma of Oropharynx

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註1

Principles of Radiotherapy

Definitive Radiotherapy

- Primary and gross adenopathy : 66 - 72 Gy (2.0-2.2 Gy/fraction)
- Low to intermediate risk : 44 - 64 Gy (2.0 Gy/fractions) in 3D RT, 54- 63 Gy (1.6-1.8 Gy/fractions)

Postoperative Radiotherapy

- Preferred interval between operation and radiotherapy is ≤ 6 weeks.
- High risk(adverse feature) : 60- 66 Gy (2.0 Gy/fraction)
- Low to intermediate risk : 44 – 64 Gy (2.0 Gy/fractions) in 3D RT, 54- 63 Gy (1.6-1.8 Gy/fractions)

CCRT or RT

- RT alone if old age, impaired renal function, poor condition or refused chemotherapy

Palliative RT

- Indicated in : relieve local symptoms, prevent debilitation such as spinal cord compression and pathological fracture, achieve durable locoregional control.

Carcinoma of Oropharynx

註2 高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page 12 (Ref. 6-10)

Principles of Chemotherapy

Concurrent with RT

Regimen 1: q3w CDDP ± Cetuximab^{註5} + RT

- Cisplatin (80-100mg/ m²) q3w during R/T
- Cetuximab(400mg/ m²) loading dose first week, then Cetuximab(250mg/ m²) maintain dose D1 + Cisplatin (80-100mg/ m²) q3w D2 during R/T

Regimen 2: Weekly CDDP ± Cetuximab^{註5} + RT

- Cisplatin (30-40mg/ m²) weekly during R/T
- Cetuximab(400mg/ m²) loading dose first week, and then Cisplatin (30-40mg/ m²) weekly D1 + Cetuximab(250mg/ m²) maintain dose D2 during R/T

Regimen 3: q3w Carboplatin^{註5} ± Cetuximab^{註5} + RT

- Carboplatin (AUC x 5mg) q3w during R/T
- Cetuximab(400mg/ m²) loading dose first week, then Cetuximab(250mg/ m²) maintain dose D1 + Carboplatin (AUC x 5mg) q3w D2 during R/T

Regimen 4: Weekly Cetuximab^{註5} + RT

- Cetuximab(400mg/ m²) loading dose first week, then Cetuximab(250mg/ m²) maintain dose during RT

Regimen5 : Carboplatin + 5-FU + Hydroxyurea (CCr < 60) + RT

- Carboplatin (AUC x 1.25mg) D1-D4
- Fluorouracil (5-FU) (850mg/m²) D1-D4
- Hydroxyurea 1CAP BID D1-D5

Regimen6 : Cisplatin + 5-FU + Hydroxyurea + RT

- Cisplatin(20mg/ m²) D1-D4
- Fluorouracil (5-FU) (850mg/m²) D1-D4
- Hydroxyurea 1CAP BID D1-D5

Carcinoma of Oropharynx

註3

高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page 13 (Ref. 11-15)

Regimens of Chemotherapy

Induction, adjuvant, 建議2-3cycles

Regimen 1: q3-4 weeks T + P ± F ± weekly Cetuximab註5

- Taxotere(60 mg/ m²) D1
- Cisplatin(60-75 mg/ m²) D1
- Fluorouracil (5-FU) (600-750mg/m²) D2-D5
- Cetuximab (400mg/ m²) loading dose first week, then Cetuximab (250mg/ m²) maintain dose

Regimen 2: q3-4 weeks Platinum ± F ± weekly Cetuximab註5

- Cisplatin(80-100mg/ m²) D1 or Cisplatin (20mg/ m²) D1-D5 or Carboplatin (AUC x 5mg) D1
- Fluorouracil (5-FU) (600-1000mg/m²) D2-D5
- Cetuximab(400mg/m²) loading dose first week, then weekly Cetuximab (250mg/ m²)

Carcinoma of Oropharynx

註3

高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page 14 (Ref. 11-15)

Regimens of Chemotherapy

Induction, adjuvant, 建議2-3cycles

Regimen 3: weekly Cetuximab^{註5}

- Cetuximab (400mg/ m²) loading dose first week, then Cetuximab (250mg/ m²) maintain dose

Regimen 4: oral Fluorouracil

- Ufur cap (tegafur 100mg+uracil 224mg) 2# BID-TID
(Salvage or palliative CT中作為取代iv-formed 5-FU之替代藥物)

Regimen 5: weekly Methotrexate

- Methotrexate (40-60mg/ m²)

Carcinoma of Oropharynx

註4

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Regimens of Chemotherapy

Recurrent, unresectable, metastatic

Regimen 1: q3-4 weeks Platinum ± F ± weekly Cetuximab^{註5}

- Cisplatin(80-100mg/ m²) D1 or Cisplatin (20mg/ m²) D1-D5 or Carboplatin (AUC x 5mg) D1
- Fluorouracil (5-FU) (600-1000 mg/m²) D2-D5
- Cetuximab(400mg/ m²) loading dose first week, then weekly Cetuximab (250mg/m²)

Regimen 2: q3 weeks Pembrolizumab ± Platinum ± F

- Pembrolizumab(200mg) D1 (if CPS ≥ 1)
- Cisplatin(80-100mg/ m²) D1 or Cisplatin (20mg/ m²) D1-D5 or Carboplatin (AUC x 5mg) D1
- Fluorouracil (5-FU) (600-1000 mg/m²) D2-D5

Regimen 3: q2 weeks Nivolumab

- Nivolumab(3mg/kg) D1

Carcinoma of Oropharynx

註4

高雄榮民總醫院 臨床診療指引 Ver.1 修訂於 2020.04.29 Page 16(Ref. 16,17)

Regimens of Chemotherapy

Recurrent, unresectable, metastatic

Regimen 4: q3-4 weeks T ± Platinum ± weekly Cetuximab^{註5}

- Taxotere(60 mg/ m²) D1
- Cisplatin(60-75 mg/ m²) D1 or Carboplatin (AUC x 5mg) D1
- Cetuximab(400mg/ m²) loading dose first week, then weekly Cetuximab (250mg/ m²)

Regimen 5: cisplatin+ epirubicin+ 5-FU+ Leucovorin

- Cisplatin (60 mg/ m²) D1
- Epirubicin (50 mg/ m²) D1
- Fluorouracil (5-FU) (2000 mg/m²) D1

Regimen 6: q2 weeks Bevacizumab

- Bevacizumab (200 mg/ m²) D1

Regimen 7: weekly Gemcitabine

- Gemcitabine (1000 mg/m²) D1

Carcinoma of Oropharynx

註5

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特殊用藥健保給付規定

Taxotere

- 頭頸部癌，限局部晚期且無遠端轉移之頭頸部鱗狀細胞癌且無法手術切除者。
- 與Cisplatin 及5-FU 併用，作為放射治療前的引導治療，限使用四個療程。

Cetuximab

- 限與放射線療法合併使用於局部晚期之口咽癌、下咽癌及喉癌患者，使用總療程以接受8次輸注為上限，需經事前審查核准後使用，且符合下列條件之一：
 1. 年齡 ≥ 70 歲
 2. $\text{Ccr} < 50\text{ml/min}$
 3. 聽力障礙者 (聽力障礙定義為500Hz、1000Hz、2000Hz 平均聽力損失大於25 分貝)
 4. 無法耐受platinum-based 化學治療
- 限無法接受局部治療之復發及/或轉移性頭頸部鱗狀細胞癌，且未曾申報 cetuximab 之病患使用。使用總療程以18週為限，每9週申請一次，需無疾病惡化情形方得繼續使用。

Carboplatin

- 限腎功能不佳 ($\text{CCr} < 60$) 或曾作單側或以上腎切除之惡性腫瘤患者使用。

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特殊用藥健保給付規定

Pembrolizumab、Nivolumab

• 先前已使用過 platinum 類化學治療失敗後，又有疾病惡化的復發或轉移性頭頸部鱗狀細胞癌成人患者。本類藥品與 cetuximab 僅能擇一使用，且治療失敗時不可互換。

• 符合下列條件：

1. 病人身體狀況良好(ECOG $\leq$ 1)
2. NYHA (the New York Heart Association) Functional Class I 或 II
3. GOT < 60U/L 及 GPT < 60U/L，且 T-bilirubin < 1.5mg/dL；Creatinine < 1.5mg/dL，
且 eGFR > 60mL/min/1.73m²
4. PD-L1 表現量 TPS $\geq$ 50%

• 初次申請以12 週為限，申請時需檢附以下資料：病理或細胞檢查報告、生物標記(PD-L1)表現量檢測報告、病人身體狀況良好(ECOG $\leq$ 1)及心肺與肝腎功能之評估資料、符合 i-RECIST 定義之影像檢查及報告(上述影像檢查之給付範圍不包括PET)、先前已接受過之治療與完整用藥資料、使用免疫檢查點抑制劑之治療計畫(treatment protocol)。

• 用藥後每 12 週評估一次，以 i-RECIST 或 mRECIST 標準評定反應，依下列原則給付：

- I. 有療效反應者(PR 及 CR)得繼續使用；
- II. 出現疾病惡化(PD)或出現中、重度或危及生命之藥物不良反應時，應停止使用；
- III. 疾病呈穩定狀態者(SD)，可持續再用藥 4 週，並於 4 週後再次評估，經再次評估若為 PR、CR 者，得再繼續使用 12 週。若仍為 SD 或已 PD 者，應停止使用。

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• 用藥後每 12 週評估一次，以 i-RECIST 或 mRECIST 標準評定反應，依下列原則給付：

- I. 有療效反應者(PR 及 CR)得繼續使用；
- II. 出現疾病惡化(PD)或出現中、重度或危及生命之藥物不良反應時，應停止使用；
- III. 疾病呈穩定狀態者(SD)，可持續再用藥 4 週，並於 4 週後再次評估，經再次評估若為 PR、CR 者，得再繼續使用 12 週。若仍為 SD 或已 PD 者，應停止使用。

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註6

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Eastern Cooperative Oncology Group (ECOG) Performance Status

Grade	Description	Suggestion
0	Normal activity fully ambulatory (無症狀)	按照標準化療評估及療程。
1	Symptoms, but nearly fully ambulatory (有症狀，完全步行，但對生活無影響)	按照標準化療評估及療程。
2	Some bed time, but needs to be in bed less than 50% of normal daytime (躺在床上的時間<50%)	按照標準化療評估及療程。
3	Needs to be in bed more than 50% of normal daytime (躺在床上的時間>50%)	可視情況考慮停止化學治療。
4	Unable to get out of bed (長期完全臥床)	建議停止化學治療。
5	Dead	

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References

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